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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, 2025

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: 001-36812

Decoy Therapeutics Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**46-5087339**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

2450 Holcombe Blvd., Suite X, Houston, TX 77021
(Address of principal executive offices)(Zip Code)

Registrant's Telephone Number, Including Area Code**: (713) 913-5608**

Securities registered pursuant to Section 12 (b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $ 0.0001	**DCOY**	**The Nasdaq Stock Market LLC**

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 Section 15(d) of the Exchange 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 the filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
Emerging Growth Company	☐		

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

Indicate by check mark whether the registrant 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 ☒

As of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock of the registrant held by non-affiliates of the registrant was $1,896,114 based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market on June 30, 2025.

As of March 17, 2026, there were 531,968 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2026 annual meeting of stockholders are incorporated by reference into Part III of the Annual Report to the extent described.

DECOY THERAPEUTICS INC.
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EXPLANATORY NOTE

On August 15, 2025, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-15 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share which became effective on that date. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the 2025 Reverse Stock Split (as defined below).

On March 5, 2026, the Company filed a Certificate of Amendment to the Company's amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-12 reverse stock split of the Company's issued and outstanding shares of Common Stock, par value $0.0001 per share, which became effective as of March 6, 2026. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the 2026 Reverse Stock Split (as defined below).

On March 13, 2026, the Company received a formal decision letter from the Nasdaq Hearings Panel granting the Company's request to continue its listing on The Nasdaq Stock Market. Previously, the Company had appealed a delisting determination issued by Nasdaq due to the Company's failure to maintain compliance with the Bid Price Rule set forth in Nasdaq Listing Rule 5550(a)(2). Pursuant to the Panel's decision, the continued listing of the Company's securities is subject to the condition that the Company must demonstrate compliance with the Bid Price Rule on or before March 20, 2026. In connection with its compliance plan, the Company completed a reverse stock split on March 6, 2026 and achieved a closing bid price of $7.47 on March 20, 2026 to regain compliance.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements made in this Annual Report on Form 10-K are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- *our ability to continue as a going concern and support our operations;*
- *our expectations regarding the timing, likelihood, expected benefits of, and potential value created by, the recently completed merger transaction between us and Legacy Decoy;*
- *the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings, commencement of preclinical studies or clinical trials of our current and future program candidates, including statements regarding the timing of our planned regulatory communications, submissions and approvals, and release of data from such studies or trials;*
- *our financial performance;*
- *our ability to maintain the listing of our shares of common stock on The Nasdaq Stock Market ("Nasdaq"), the potential liquidity and trading of such shares of common stock and our ability to maintain continued listing with the Nasdaq listing standards;*
- *our ability to successfully manage our cash and cash equivalents and any anticipated proceeds from financing transactions;*
- *our ability to acquire sufficient sources of funding if and when needed;*
- *our estimates and expectations as to expenses, ongoing losses, future revenue, cash flow, capital requirements and our need for or ability to obtain additional funding before we can expect to generate any revenue from product sales*
- *our belief regarding the sufficiency of our cash resources to support our operations;*
- *our liquidity position and the expected sufficiency of such position for anticipated operating and capital requirements;*
- *our plans to develop and commercialize potential product candidates, including planned preclinical, clinical, regulatory, commercialization and manufacturing activities;*
- *our expectations regarding the scope of any approved indication for any product candidate, if approved;*
- *the attraction and retention of highly qualified personnel;*
- *the ability to protect and enhance our products and intellectual property;*
- *developments and projections relating to our competitors or industry;*
- *our relationships and actions with third parties;*
- *future regulatory, judicial and legislative changes in our industry; and*
- *any other statements of expectations, plans, intentions or beliefs, and any statements of assumptions underlying any of the foregoing.*

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should," "would," "target", "potential," "evaluate," "proceeding."

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements:

- *the risk that the recently contemplated merger transaction with Legacy Decoy may not enhance stockholder value and may adversely affect our operating results, business or investor perceptions;*
- *our ability to raise additional funds when necessary, and/or on acceptable terms;*
- *the adequacy of our capital to support our future operations;*
- *our ability to obtain and maintain regulatory approvals for our potential product candidates;*
- *the potential impact of changes and disruptions at the FDA, including a reduction in the FDA's workforce and/or decreased funding for the FDA, on our business;*
- *our ability to identify patients that can be treated by our potential product candidates and to enroll these patients in our clinical trials;*
- *our ability to successfully commercialize our potential product candidates, if approved.*
- *our ability to leverage technology to identify and develop future potential product candidates;*
- *fluctuations in our operating results; and*
- *other factors described in our filings with the SEC.*

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of this Annual Report on Form 10-K describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those discussed at length in the section titled "Risk Factors." These risks include, among others, the following:

Risks Related to our Business

- Our common stock may be subject to delisting from Nasdaq.
- Our financial condition raises substantial doubt regarding our ability to continue as a going concern.
- We have never generated revenue from product sales, and all of our potential product candidates are currently in the preclinical stage, and we may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.
- Because we have yet to generate revenue from product sales on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our prospects and the likelihood of success or failure of our business.
- Because early-stage drug development requires major capital investment, as we continue to incur operating losses, we will need to raise additional capital or form strategic partnerships to support our research and development activities in the future.

Risks Related to the Discovery, Development and Commercialization of Potential Product Candidates

- If any strategic alliances on which we depend are unsuccessful or are terminated, we may be unable to develop or commercialize certain potential product candidates and we may be unable to generate revenues from our development programs.
- Since we expect to rely on third parties to conduct, supervise and monitor any future clinical trials, if those third parties fail to perform in a satisfactory manner and one that meets applicable regulatory, scientific and safety requirements, it may materially harm our business.
- Because the approach we are taking to discover and develop drugs is novel, including the use of artificial intelligence, it may never lead to marketable products, and we are subject to unique risks related to evolving AI regulations in the U.S. and internationally, third-party technology dependencies, intellectual property concerns, and cybersecurity threats associated with our use of AI technology.
- Even if FDA grants breakthrough therapy designation for one or more of our potential product candidates, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our potential product candidates will receive marketing approval, and FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for breakthrough therapy.
- If we do not succeed in our efforts to identify or discover additional potential product candidates, your investment may be lost.
- Our potential product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.
- Difficulty in enrolling patients is a common hurdle faced by early-stage biotechnology companies and could, and often does, delay or prevent clinical trials of potential product candidates.

Risks Related to Our Operations and Industry

- Our reliance on patents, trade secrets and confidentiality agreements may not adequately protect our intellectual property, and third parties may challenge the validity or enforceability of our patents or design around our claims.
- Our trade secrets and confidential proprietary information may be disclosed, and competitors may gain access to our trade secrets or independently develop substantially equivalent information and techniques.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- We may not be able to protect our intellectual property rights throughout the world.

- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our potential product candidates, we may be unable to generate any revenues from product sales.
- If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel, or experience increases in our compensation costs, our business may materially suffer.
- If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.
- We may face potential product liability, and if successful claims are brought against us, we may incur substantial liability and costs which could be greater than our insurance coverage or overall resources.

Risks Related to Ownership of our Common Stock

- The price of our common stock may fluctuate substantially.
- Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of our common stock or cause our stock price to decline.
- We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.
- If we were deemed to be an investment company under the Investment Company Act of 1940, as amended (the "1940 Act"), applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.
- We are a "smaller reporting company" and are able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.
- Our certificate of incorporation, our bylaws, and Delaware law may have anti-takeover effects that could discourage, delay, or prevent a change in control, which may cause our stock price to decline.
- Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management is required to devote substantial time to compliance matters.

General Risk Factors

- If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.
- If we fail to comply with the rules under the Sarbanes-Oxley Act related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.
- Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our business, results of operations, financial condition and cash flows.
- Additional indirect taxes in various jurisdictions could materially adversely affect our business, financial condition, results of operations, and prospects.

Part I

Item 1. Business

Unless the context otherwise requires, "Company," "we," "us," and "our" refer to the combined organization, Decoy Therapeutics Inc. ("Decoy", formerly known as Salarius Pharmaceuticals, Inc. ("Salarius")), and, where appropriate, its consolidated subsidiaries. References to "Legacy Decoy" refer to Decoy Therapeutics Inc. prior to the Merger (as defined below), which became a wholly owned subsidiary of the Company as a result of the Merger. References to "Notes" refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

Overview

We are a pre-clinical stage biotechnology company focused on advancing our pipeline of peptide conjugate therapeutics engineered through our proprietary IMP^{3}ACT™ platform. Our IMP^{3}ACT™ platform represents a paradigm shift in peptide conjugate drug discovery and manufacturing, leveraging machine learning ("ML") and artificial intelligence ("AI") tools alongside high-speed synthesis techniques to rapidly engineer, optimize and manufacture peptide conjugates that target serious unmet medical needs. Peptide conjugates are emerging as a major therapeutic drug modality, with the potential to transform multiple therapeutic areas. Utilizing our novel IMP^{3}ACT platform that increases the drug development speed and reduce the complexity of variant synthesis, we aim to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology, with the goal of becoming a fully integrated biopharmaceutical company at the forefront of this field. Through this approach, we intend to revolutionize the design, development, and commercialization of peptide conjugate therapeutics. We have no products approved for commercial sales and have not generated any revenue from product sales.

Prior to January 8, 2026, we were known as Salarius Pharmaceuticals, Inc. ("Salarius"). In November 2025, Salarius completed a Merger (as defined below) with Legacy Decoy and conducted financings to raise capital for its business (together, along with future steps set forth elsewhere in this 10-K annual report, the "Decoy Transaction"). We refer herein to the post-transaction entity as the "Combined Company." In connection with the Decoy Transaction, on January 8, 2026, Salarius filed an amendment to its amended and restated certificate of incorporation to change its name to Decoy Therapeutics Inc. (the "Name Change"). Prior to the Name Change, the Combined Company's shares of common stock traded on the Nasdaq Capital Market ("Nasdaq") under the symbol "SLRX." Following the Name Change, the Combined Company's shares of common stock now trade on the Nasdaq under the symbol "DCOY."

The Merger (as defined below) combines our complementary approaches to create a comprehensive drug development platform. The Decoy IMP³ACT platform is generating a pipeline of Designable Multi-Antivirals ("D-MAV") candidates across respiratory viruses, designed to be extended, not rebuilt, when the next threat emerges. Additionally, two small molecule drugs that address gene dysregulation: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat ("SP-2577"), a targeted protein inhibitor are legacy Salarius clinical candidates. We supported The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored clinical trial evaluating SP-2577 in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia through December, 2025. No further enrollment is planned. We intend to seek strategic alternatives for this program including potential out-licensing.

We plan to integrate SP-3164 to expand our opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras ("P-PROTACs"). We believe the synergies from the Merger are evident in our combined approach to drug development, integrating expertise in peptide conjugates with our small molecule assets. This combination enables us to address a wider range of diseases and potentially "undruggable" targets.

Recent Developments

Nasdaq Listing

On December 31, 2025, the Company received written notice from Nasdaq that it was not in compliance with Nasdaq Listing Rule 5550(a)(2) because the closing bid price of the Company's common stock for the last 30 consecutive business days was below the $1.00 per share minimum bid price requirement (the "Minimum Bid Price Requirement"). The Company appealed the delisting determination by requesting a hearing before a Nasdaq Hearings Panel (the "Hearings Panel"). The company presented its appeal to the Hearings Panel in early February 2026 and submitted a plan to regain compliance by March 20, 2026, including conducting a reverse stock split.

On March 13, 2026, the Company received a written notice from the Hearings Panel notifying the Company that it has been granted until March 20, 2026 to regain compliance with the Minimum Bid Price Requirement. Pursuant to the Hearings Panel's decision, the continued listing of the Company's securities is subject to the condition that the Company must demonstrate compliance with the Minimum Bid Price Requirement on or before March 20, 2026. In connection with its compliance plan, the Company completed the 2026 Reverse Stock Split (as defined below) on March 6, 2026, and subsequently achieved a closing bid price of $7.47 on March 20, 2026, thereby demonstrating compliance with the Minimum Bid Price Requirement.

Closing of Decoy Merger

On January 10, 2025, the Company entered into an Agreement and Plan of Merger, as amended by the First Amendment on March 28, 2025, by the Second Amendment on June 10, 2025, by the Third Amendment on July 18, 2025, by the Fourth Amendment on July 29, 2025, and by the Fifth Amendment dated September 17, 2025 (as amended, collectively, the "Merger Agreement") with Decoy Therapeutics MergerSub I, Inc. ("MergerSub I"), Decoy Therapeutics MergerSub II, LLC ("MergerSub II"), and Legacy Decoy. On November 12, 2025, pursuant to the Merger Agreement, MergerSub I merged with and into Legacy Decoy, and immediately thereafter Legacy Decoy merged with and into MergerSub II (the "Merger"), resulting in the Legacy Decoy business becoming a wholly owned subsidiary of the Company.

In connection with the Merger, the Company issued 877.709 shares of the Series A Preferred Stock and 796.306 shares of the Series B Preferred Stock to former Legacy Decoy stockholders and debtholders and reserved 45.098 shares of Series A Preferred Stock for assumed in-the-money options and warrants of Legacy Decoy. In connection with the adjustment to the conversion ratio in the certificate of designations for the Series A and Series B Preferred Stock triggered by the offering, the number of Company common shares underlying the issued and reserved shares of Series A and Series B Preferred Stock is 401,126. The shares of Series A Preferred Stock and Series B Preferred Stock are not convertible into common stock until such time as the Company's stockholders approve such conversion in accordance with Nasdaq Rule 5635 and the approval of the Company's initial listing application with Nasdaq. When converted, the conversion ratio pursuant to which the new common shares will be issued has been adjusted pursuant to the 2026 Reverse Stock Split (as defined below) ratio of 1-for-12.

Management and Director Changes

In connection with the Merger closing on November 12, 2025, Mr. Frederick E. Pierce was appointed Chief Executive Officer and Director; Dr. Barbara Hibner was appointed Chief Scientific Officer; and Mr. Peter Marschel was appointed Chief Business Officer. Mr. Mark Rosenblum will continue to serve as Executive Vice President and Chief Financial Officer (including as principal financial officer and principal accounting officer).

November 2025 Financing

On November 11, 2025, we entered into an underwriting agreement (the "Underwriting Agreement") with Ladenburg Thalmann & Co. Inc., as the sole underwriter (the "Representative"), relating to the issuance and sale in a public offering (the "November 2025 Offering") of: (i) 209,528 shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), (ii) pre-funded warrants to purchase up to 179,361 shares of Common Stock, (iii) Series A warrants to purchase up to 388,889 shares of Common Stock, (iv) Series B warrants to purchase up to 388,889 shares of Common Stock, and (v) up to 699,999 additional shares of Common Stock, Series A warrants to purchase up to an additional 699,999 shares of Common Stock and Series B warrants to purchase up to an additional 699,999 shares of Common Stock that may be purchased pursuant to a 45-day option to purchase additional securities granted to the Representative by the Company. The Representative exercised this option on November 11, 2025 for 55,477 shares of Common Stock, Series A warrants to purchase up to 58,333 shares of Common Stock and Series B warrants to purchase up to 58,333 shares of Common Stock. The combined public offering price of each share of Common Stock, together with the accompanying Series A warrants and Series B warrants, was $18, less underwriting discounts and commissions. The combined public offering price of each pre-funded warrant, together with the accompanying Series A warrants and Series B warrants, was $17.9988, less underwriting discounts and commissions. Subject to limited exceptions, a warrant holder may not exercise any portion of its warrants to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder prior to the date of issuance, 9.99%) of the Company's outstanding Common Stock after exercise.

The November 2025 Offering, including the additional shares of Common Stock, Series A warrants and Series B warrants sold pursuant to the exercise of the Representative's option, closed on November 12, 2025.

The net proceeds from the Offering, including the additional shares of Common Stock, Series A warrants and Series B warrants sold pursuant to the exercise of the Representative's option, after deducting underwriting discounts and commissions and other estimated Offering expenses payable by the Company and excluding any net proceeds from the exercise of the Series A warrants, Series B warrants and pre-funded warrants, were approximately $6.3 million.

In connection with the November 2025 Offering, the Company and Equiniti Trust Company, LLC entered into a Warrant Agency Agreement pursuant to which Equiniti agreed to act as warrant agent with respect to the Series A warrants, the Series B warrants and the pre-funded warrants.

On November 12, 2025, pursuant to the Underwriting Agreement, the Company issued warrants to the Representative to purchase up to 22,218 shares of Common Stock at an exercise price of $27.90, subject to adjustments (the "Representative Warrants"). The Representative Warrants are exercisable at any time and from time to time, in whole or in part, until November 11, 2030, and have substantially similar terms to the Series A warrants.

All securities issued in the November 2025 Offering (including the shares of Common Stock issuable from time to time upon exercise of the warrants and the Representative Warrants) were offered pursuant to a registration statement on Form S-1, as amended, which became effective on November 10, 2025.

Reverse Stock Splits

On August 15, 2025, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-15 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "2025 Reverse Stock Split") which became effective on that date. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the 2025 Reverse Stock Split.

On March 5, 2026, the Company filed a Certificate of Amendment to the Company's amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-12 reverse stock split of the Company's issued and outstanding shares of Common Stock, par value $0.0001 per share (the "2026

Reverse Stock Split") which became effective as of March 6, 2026. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the 2026 Reverse Stock Split.

Strategy

Decoy focuses on viral diseases that drive widespread health, economic and societal disruption, shaping programs not only around scientific potential, but around affordability, reimbursement, and the ability to reach patients at scale.

Our IMP³ACT platform creates peptides that target what enveloped viruses share, integrating AI-enabled peptide design with rapid synthesis to advance candidates faster than traditional approaches. What that means in practice:

- AI-accelerated design that learns and improves with each candidate
- Research synthesis timelines measured in days, not months
- A proprietary data advantage that compounds across programs
- Built-in adaptability to novel and emerging viral threats
- Faster time to market, and potential for follow-on indications

We select D-MAV targets based on the following criteria:

- Potential for a therapeutic that can address multiple disease indications with one drug.
- The presence of a natural "starting peptide" that our platform can rapidly optimize into a promising therapeutic.
- Potential to create a peptide conjugate therapeutic with a novel and differentiated value proposition that meets a significant unmet medical need.

We believe this target selection strategy will maximize return on investment from the IMP^{3}ACT platform by efficiently advancing paradigm-creating D-MAVs, changing the way we protect against and treat viral diseases.

Our goal is to become a fully integrated biopharmaceutical company with a pipeline of novel therapeutics. We intend to achieve this through the following strategic objectives:

- Achieve clinical proof-of-concept by bringing our lead pan-Coronavirus antiviral forward through a Phase 2 human challenge trial. Despite COVID-19 moving to an endemic phase, significant global unmet medical need remains among immune-suppressed populations. To date, this program has been largely supported by non-dilutive funds, and we believe the program will continue to attract such funds to advance this program clinically.
- Bring forward one additional transformative program to IND-enabling status within two years, leveraging our platform's speed and efficiency to advance potentially transformative peptide conjugate therapeutics meeting our target selection criteria.
- Build a platform manufacturing capability: We intend to pursue collaborations with major commercial peptide manufacturing organizations, allowing rapid scale-up of novel D-MAV drug candidates for pre-clinical and clinical studies in a repeatable, cost-effective manner.

- Continue to access non-dilutive funding. To date, we have attracted significant non-dilutive funding from The Gates Foundation, BARDA, Google, and the IMI-Care Consortium, and expect to continue to seek such funds.

- Pursue value-enhancing partnerships. We believe we can rapidly create and validate novel therapeutic assets, and aim to attract capital and capabilities in later-stage development and commercialization through selective partnerships.

- Maintain Pandemic Readiness: preserve the pandemic "Call-Option" embedded with the IMP^{3}ACT Platform. Our platform is well-positioned to rapidly advance antiviral therapeutics in response to novel viral pathogens, especially in viral families considered most likely sources of such pathogens (e.g., avian influenza). We will continue to work with governmental and non-governmental organizations to provide funding for developing D-MAVs against global threats. Given financial returns from therapeutic assets like mRNA vaccines and Paxlovid during COVID-19, we consider this capability a valuable 'Call Option' on the next epidemic or pandemic.

Program Development

We intend to leverage the proprietary compound SP-3164, which binds to the E3 ligase complex CRLCBRN, together with our peptide engineering platform to create 'peptide-based Proteolysis Targeting Chimeras' ("PROTACs", "P-PROTACS").

PROTACs are typically bifunctional molecules: one side binds to a targeted protein while the other binds to an E3 ligase, with a linker between the two. When both are brought together, the targeted protein is ubiquitinated ("tagged") by the E3 ligase and marked for destruction via proteasomal degradation. SP-3164, a novel immunomodulatory drug molecule, has advantageous properties including potent cereblon binding, low molecular weight, high oral bioavailability, and well-characterized binding mechanisms. Using IMP^{3}ACT platform-engineered peptides instead of small molecules to target disease-causing proteins offers several advantages: peptides can be precisely engineered to bind specifically to one protein or a pre-determined set (e.g., across mutated Ras proteins), whereas small molecules typically bind to many "off-target" proteins, decreasing selectivity and increasing toxicity. Peptides can bind to the active enzymatic site or be engineered to bind to other sites under lower selective mutational pressure, reducing resistance mechanisms. We believe using peptides instead of small molecules vastly expands protein targeting opportunities and dramatically shortens P-PROTAC candidate development timelines.

The PROTAC mechanism is "event-driven"-one PROTAC molecule can induce degradation of multiple copies of the protein target. Even small concentrations can be highly effective, potentially avoiding toxicity from high drug concentrations. By degrading rather than inhibiting the protein target, both enzymatic and other functions are disrupted, with effects lasting until the cell synthesizes new proteins-dramatically expanding duration of action. P-PROTACs are an exploratory arm of the IMP³ACT platform, applying D-MAV design principles to intracellular viral and host protein targets, including those considered undruggable. Early investigative programs are underway, deepening the D-MAV antiviral thesis into a new modality.

Drug Development Programs

We are developing D-MAVs (designable multi-antivirals) targeting the conserved fusion mechanism shared across enveloped virus families. We have demonstrated multi-virus in vitro and in vivo activity. The same platform and design tools will support early investigative antiviral P-PROTAC candidates.

- COV: Pan-Coronavirus Prophylactic for Immunocompromised Patients. Our lead program, a nasally inhaled pan-Coronavirus prophylactic, has demonstrated in vitro activity against all human-infecting Coronaviruses tested, including representatives of all variant strains of concern of COVID-19 that have emerged as of the date of this report. This program has primarily been funded by grants from The Gates

Foundation, the Center for the Biologic Advanced Research and Development Authority's Blue Knight Program ("BARDA"), and support from the IMI Care Consortium, Google, and NVIDIA computing programs. The Company plans to file an Investigational New Drug ("IND") application with the United States Food and Drug Administration ("FDA") or the European equivalent clinical trial application ("CTA") during the first half of 2027 and to continue to pursue non-dilutive funding and a development partner for clinical development.

- TRI: Broad Respiratory Antiviral (Flu/COVID-19/RSV). We aim to exploit structural similarities across these three viral families to create a peptide conjugate antiviral broadly applicable to most influenza-like-illnesses ("ILI"), which drive an estimated 15 to 20 million medical visits annually in the United States alone. Building on our work creating peptide conjugate antivirals with broad activity in the Coronavirus and Paramyxovirus (RSV) viral families, we believe this program could represent a fundamental shift in respiratory virus treatment.

Our Exploratory Stage Program

P-TAC: Exploratory P-PROTAC Conjugates: We aim to explore the use of SP-3164 as the E3 ligase binding component in peptide based PROTACs, using engineered peptides to target intracellular proteins involved in viral replication and latent virus activation.

Legacy Small Molecule Program

SP-2577: SP-2577 is a legacy small molecule LSD-1 inhibitor program from pre-Merger Salarius' portfolio. As a legacy product, it does not utilize Legacy Decoy's integrated technology. We intend to continue monitoring The University of Texas MD Anderson Cancer Center ("MDACC") in its sponsored investigator-initiated clinical trial evaluating seclidemstat (SP-2577) in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia. In July 2024, the FDA placed the trial on partial clinical hold following a serious grade 4 adverse event. In February 2025, we announced that MDACC had addressed the FDA's questions and the partial clinical hold was lifted, with patient enrollment resumed. Enrollment for this clinical trial ended in January of 2026; we intend to seek strategic alternatives for this program including potential out-licensing.

Grant Agreements

The grant agreement between Legacy Decoy and The Gates Foundation (the "Gates Grant Agreement") was entered into on September 9, 2021 and subsequently amended on August 29, 2023 and February 26, 2025, entitling us to approximately $5 million in the aggregate. We have received approximately $4.4 million in multiple tranches as we reached specific research milestones, and expect to receive the final tranche of approximately $600,000 in the first half of 2026. The use of grant funds is governed by a budget approved in conjunction with The Gates Foundation, and material deviations (i.e., 10%) require their approval. The expiration date is December 31, 2026. The Gates Foundation may modify, suspend, discontinue, or terminate the Gates Grant Agreement if: (a) not reasonably satisfied with our progress; (b) significant changes to leadership or other factors threaten the project's success; (c) a change in control occurs; (d) a change in our tax status; or (e) we fail to comply with the agreement. Any unused funds must be returned promptly upon expiration or termination.

We have received multiple awards from the BLUE KNIGHT™ Resident QuickFire Challenge (the "QFC") and entered into letter agreements with Johnson & Johnson Innovation LLC ("JJI") on January 31, 2023, July 28, 2023, and March 11, 2024 to investigate various ancillary program elements. We have supplied final reports for all three grants in accordance with the letter agreements.

Market Opportunity for Our Current Drug Development Programs

We see opportunities in each of the four main areas of our drug discovery program efforts:

COV: Pan-Coronavirus Inhibitor for Immunocompromised Patients

According to the December 2024 World Health Organization publication on COVID-19, SARS-CoV-2 continues to infect and cause severe acute disease and post COVID-19 condition (long COVID).[1]Current tools include mRNA vaccines and Paxlovid, which are effective at avoiding severe outcomes in high-risk patients. However, Paxlovid cannot be used prophylactically and has a significant Drug-Drug Interaction[2](“DDI”) profile, leaving a treatment gap for immune-suppressed patients or those with high-risk comorbidities who do not respond significantly to vaccines. Early pandemic antibody prophylactics like Evusheld became obsolete due to rapid SARS-CoV-2 evolution. The recently authorized prophylactic antibody Pemgarda is at risk of losing efficacy as the virus continues to mutate-the most recent variants have approximately 150 mutations compared to the original viral sample.

We commissioned market research in 2022[3] that indicated important unmet medical needs in COVID-19 treatment and prevention:

- Prophylaxis for current and future variants in high-risk patients: Health care providers (“HCPs”) are concerned about preventing severe cases in at-risk patients, particularly critical if new variants arise.

- Easy-to-use route of administration: Key opinion leaders noted the need for non-injectable preventative products to enable broad availability and avoid high-risk patients visiting healthcare facilities for administration.

- Effective treatments with better Drug-Drug Interaction ("DDI") profile: DDIs, such as those with Paxlovid, are a concern for HCPs, especially given that high-risk patients tend to have comorbidities and are likely on other treatments.

This market research, which included HCP and payer studies across the United States and European Union, indicated that 20 million or more patients in the U.S. and Europe are at ‘highest risk’ from COVID-19 and other respiratory viral infections, with favorable reimbursement outlook for therapeutics filling treatment gaps.

Our lead program is a broad-acting antiviral nasal spray to prevent or mitigate COVID-19 infections in high-risk, immunocompromised populations with limited treatment options. This agent has shown in vitro activity against all human-infecting Coronaviruses, including all COVID-19 variants to date, would be conveniently self-administered, and is expected to provide 8-24 hours of antiviral activity with low cost of goods.

We expect multiple potential attractive development and commercialization options for an inhaled pan-Coronavirus fusion inhibitor, including:

- Pre- and post-exposure prophylaxis (“PrEP”/”PEP”) for highly immunocompromised populations facing elevated risks from severe immune deficiencies associated with hematological malignancies and immunosuppressive medical treatments in hematopoietic stem cell transplantation and solid organ transplants, with potential for label expansion. Market research suggests over 5 million such patients in the U.S. and EU, with an estimated net price of up to $500 per 30-day supply in the U.S. feasible.

- Post-infection treatment as an alternative to Paxlovid with a superior DDI profile. Morningstar projects full year 2024 revenues exceeding $5 billion[1] for Paxlovid, despite notable DDIs with widely prescribed drugs such as statins (over 90 million Americans) and calcium channel blockers (more than 20 million Americans). Many high-risk patients cannot take Paxlovid due to DDI concerns. Paxlovid’s U.S. list price is $1,390 for a 5-day course[2] as of October 18, 2023.

We also believe there may be additional opportunities for a pan-Coronavirus fusion inhibitor to generate revenue from public health authority stockpiling of drug for pandemic preparedness and military readiness purposes.

Our plan is to initially develop this agent as a pre- and post-exposure prophylactic for targeted immunocompromised subsets, such as patients with hematological malignancies and post-transplant patients, who have high unmet medical need and can be accessed in the U.S. by a small, specialized sales force focusing on cancer treatment and transplant centers. We then plan to expand to additional indications.

We recognize the rapid evolution of the COVID landscape and will continue to engage key opinion leaders, health care providers, payers, and patient market research and potentially adjust our plans based on those findings.

[1] https://www.who.int/publications/m/item/covid-19-epidemiological-update---24-december-2024
[2] https://paxlovid.pfizerpro.com/drug-interactions
[3] Primary market research performed by Bionest Partners in Oct/Nov 2022: 13 HCPs, 13 Payers in the US, DE, FR, IT, and the U.K.

TRI: Broad Respiratory Antiviral (Flu/COVID/RSV)

We are engineering a groundbreaking approach to combat Flu/COVID/RSV infections with a single D-MAV antiviral potentially effective against all three major respiratory viruses, including pandemic flu strains if possible.

By addressing three viral families with a single therapy, we aim to revolutionize respiratory illness management. Respiratory tract infections represent a significant unmet medical need. The seasonal convergence of influenza, respiratory syncytial virus ("RSV"), and COVID-19 (the "tripledemic") has intensified the burden of these infections, which are often vectors to dangerous lower respiratory infections. Despite vaccine availability, with decreasing uptake, hospitalizations and fatalities from respiratory viruses continue to strain healthcare resources.

Our single therapy with broad activity approach potentially offers several key advantages:

- A single therapy with proven efficacy against all three viruses could potentially eliminate the need for multiple treatments, streamlining patient care and reducing complexity for healthcare providers.
- Our therapy is expected to be self-administered, offering convenience and autonomy to patients.
- Peptide conjugates to date have a favorable safety and tolerability profile.

Given the expected ease of use and safety profile, we intend to pursue a commercialization approach that will make this product, if approved, broadly accessible to symptomatic patients, leveraging emerging channels such as telehealth, digital patient engagement, and at-home delivery.

In the United States, the combined impact of influenza, RSV, and COVID-19 results in an estimated 15 to 20 million medical visits annually among patients aged 18 and older. This significant healthcare utilization underscores the burden of respiratory tract infections on the healthcare system.

Expanding the market to include individuals with symptomatic illness who may not physically visit a doctor's office approximately doubles the number of eligible adult patients. With the increasing adoption of telehealth services and the advancement of wearables signaling very early respiratory infections, there is a tangible opportunity to expand the market for respiratory tract infection treatments beyond patients who traditionally seek in-person medical care.

Given these factors, we believe our 'tripledemic' D-MAV antiviral program could represent the cornerstone of a significant global franchise.

Our IMP^{3}ACT Platform

Overview of Peptides and Peptide Conjugate Therapeutics

A key advantage of D-MAVs engineered by our IMP^{3}ACT Platform is 'polypharmacology,' in which a single molecule can activate or inhibit multiple targets/receptors in an additive or synergistic manner to achieve superior or multi-indication efficacy.

The success of multi-targeting peptide conjugates is due to careful peptide design based on structural similarity between viruses, an advantage difficult to match with other modalities, and in contrast to the often unpredictable off-target effects of small molecules.

An FDA-approved polypharmacology example is Eli Lilly's blockbuster ZepBound™, a single peptide conjugate demonstrating agonism of both GLP-1R and gastric inhibitory peptide receptor. Another example is our lead program, a D-MAV demonstrating activity against multiple human infecting coronaviruses.

Peptides are short chains of amino acids linked by peptide (amide) bonds, typically less than 50 amino acids long, playing vital roles in biological processes.[4] Secondary interactions cause peptides to fold into complex 3-dimensional structures, including the common α-helical coil. α-helical peptides and proteins are ubiquitous in biology, and α-helices often interact chemically with other α-helices driving protein-protein and protein-nucleic acid interactions, making α-helical peptides effective therapeutic bases.

Peptides have important advantages compared to small molecules and antibody-based therapeutics[5]:

- High potency and specificity: Peptides bind a larger surface area of the target than small molecules, providing high selectivity with tight binding.
- Excellent safety profile with predictable metabolism: Small molecules easily diffuse across cell membranes and often have off-target toxicities. Peptides typically do not passively diffuse and are usually metabolized into non-toxic compounds.
- High tissue penetration vs. antibodies: Antibody-based therapeutics are very large (~30x the size of peptides) and have difficulty diffusing deep into tissues from blood vessels.
- Simpler manufacturing, lower cost of goods: Peptides are manufactured using synthetic chemistry, whereas antibody-based therapeutics require complex, intensively regulated biological processes.

Small peptides as drugs, however, have an intrinsic limitation; they are subject to rapid enzymatic digestion and clearance from the GI tract or in the bloodstream, limiting their half-life and oral bioavailability.

Peptide conjugates solve this problem by chemically linking a peptide, typically via a polyethylene glycol (PEG) structure, to additional molecules (e.g., another peptide, nucleic acid, or fatty acid), enhancing drug-like properties by improving enzymatic stability, half-life, and bioavailability while maintaining low immunogenicity.

The IMP^{3}ACT *Platform*

The Immediate Peptide/PPMO/P-PROTAC Alpha-helical Conjugate Technology ("IMP^{3}ACT") platform leverages peptide 'coiled-coils' chemistry and physics to design α-helical peptides through computational and ML tools. Starting from naturally existing peptide ligands, we optimize their structure and transform them into multimeric conjugates by chemically linking peptides to lipids and other anchor moieties, enhancing drug-like properties with extended pharmacokinetics. Our technology has produced single peptide conjugates active against multiple human coronaviruses, including all SARS-CoV-2 major variants to date, and a second conjugate active against RSV A, RSV B, and hPIV3. By integrating ML algorithms to assist in peptide design and synthesis, our platform accelerates creation of lead molecules for preclinical evaluations, simultaneously optimizing for enhanced affinity, binding specificity, protease resistance, pharmacokinetic properties, and manufacturability.

Our IMP^{3}ACT platform may achieve peptide conjugate manufacturing readiness faster than conventional processes, reducing costs and accelerating delivery of broad-spectrum drug candidates to IND. The modular nature means each new drug candidate improves the overall platform, and success likelihood should grow as the ML/AI models learn. By employing solid phase peptide synthesis in an "All-in-One" manufacturing approach, we optimize assembly of complex peptide-linker-functionalized compounds, enhancing platform speed, efficiency, and predictive value.

The Design-Build-Test-Learn Engine

We have integrated advancements in data science, peptide conjugate chemistry, and manufacturing processes to create our IMP^{3}ACT platform. The core is the Design-Build-Test-Learn Cycle: "Design" utilizes AI in silico approaches to analyze protein and genomics datasets and make structure-function predictions; "Build" implements fast-flow synthesizers generating peptide candidates faster than industry standard; "Test" incorporates experimental testing via reliable assays to characterize peptide-candidates; and "Learn" capitalizes on experimental data to redesign improved in silico candidates.

This integrated, multiparameter approach streamlines drug discovery, making it faster and more efficient with greater attention to drug-like and commercialization properties. Continuing to iterate on our Design-Build-Test-Learn loop will generate valuable proprietary data driving in silico models to generate design solutions otherwise unavailable from computational approaches. Our hypothesis is that the key to ML/AI-driven drug design value-creation is well-structured, useful, proprietary data and knowledge on which tools to use-not the computational models themselves. Our platform strategy will help us become leaders in designing and developing α-helical D-MAV peptide-conjugate therapeutics.

Starting from Existing Peptide Ligands

A key platform strategy element is starting from naturally existing peptides, leveraging 'nature's starting points' to improve program timelines and reduce risk. We can rapidly synthesize a D-MAV incorporating a naturally existing peptide sequence that is immediately active against the target in question. We believe this is an excellent starting point for the Design-Build-Test-Learn loop because it significantly decreases the size of the peptide conjugate design space, making it computationally tractable to rapidly optimize for drug-like properties.

Our in silico engine uses ML, AI, and physics-based computational tools to identify helical motifs within metagenomics data shared across targets. This enables rapid design of polypharmacologic peptide conjugates where one drug can interact with multiple targets, unlocking broad activity across several indications from a single conjugate. These ML-driven α-helical drug candidates can inhibit a wide range of viruses by targeting shared viral fusion machinery, critical for enveloped virus entry and replication. We will leverage the virally trained α-helical database to explore targeting intracellular viral targets with innovatively designed P-PROTACs incorporating the Salarius molecular degrader, SP-3164.

Multiparameter Optimization of Drug Properties

The IMP^{3}ACT Platform acts as an iterative feedback loop and incorporates data from multiple in vitro experiments to improve candidate peptide design parameters. The platform is designed to optimize against multiple parameters simultaneously. Traditional drug development relied on 'one step at a time' optimization, often leading to restricted chemical design space where important downstream attributes like pharmacokinetic behavior cannot be easily enhanced. By using all experimental data relevant to making a drug to train the ML engine, more drug-like peptide conjugates with optimized functionality and commercialization potential may be designed. This multiparameter optimization reduces costs and significantly decreases probability of pre-clinical or clinical failures by avoiding 'dead end' development paths.

Rapid synthesis

We use fast-flow automated process coupled with a proprietary "All-in-One" method (patent pending) to synthesize multiple peptide-conjugates on lab-based machines. The yield (5-100 mg depending on desired scale) and purity is sufficient for multiple in vitro tests including physicochemical properties and biological function. This innovation dramatically decreases cycle time to learn structure-activity relationships for different peptide designs and enables construction of a multiparameter structure-activity-drug-like proprietary database on α-helical peptides.

Compared to standard industrial solid phase synthesis, fast-flow synthesis leverages a heated reactor to accelerate speed, allowing amide bond formation creation in just 7 seconds per amino acid, compared to around 1 hour per cycle traditionally. Fast-flow synthesis can be automated to eliminate human intervention and errors and work in high throughput fashion. Mijalis et al demonstrated fast-flow machines can generate peptides 45 times faster than standard batch synthesis (40 minutes versus 30 hours[6]) with better crude peptide output and yields. This automated approach enables rapid peptide conjugate production while maintaining high quality, shortening overall time to optimize clinical drug candidates.

We have invented a multi-arm linker compatible with solid phase peptide synthesis methods that can build complex biomacromolecules containing branched peptides and other functionalities in one synthetic run. These molecules can be differentially functionalized while attached to solid phase resin; our proprietary “All-In-One” manufacturing. When the desired molecule is built, the intact, desired compound can be cleaved from the resin, purified, and isolated for formulation and administration.

Using fast-flow synthesis with this process, the research scale synthesis of a peptide conjugate is reduced from several months (typical at a standard CDMO) to days or hours. Our IMP^{3}ACT platform is a unique lead optimization engine that can rapidly design from natural peptide ligands and identify optimized drug-like lead molecules. Additionally, we are currently evaluating the use of our “All-In-One” process at commercial scale for further time savings in the transition from preclinical to GLP and cGMP scale-up.

Testing

We focus on using in silico and empirical assays with predictive value. In the design engine, in silico tools have been validated against actual data (e.g., binding affinity, solubility, protease resistance, manufacturability) to ensure reliability. The screening cascade for each program relies on predictive assays to streamline decision making. Where possible, human organoid and epithelial tissue models are incorporated to improve predictive power, as rodent models have moderate predictive value and translation to human tissues is difficult, especially for intranasal or inhaled programs. Organoid models are also significantly less expensive and easier to scale than animal models.

The human airway epithelial (“HAE”) model is a cell culture system grown at an air-liquid interface (“ALI”). This in vitro culture system mimics human airway epithelium more closely than traditional submerged cell cultures. In the ALI setup, the basal surface of human airway cells contacts a liquid culture medium while the apical surface is exposed to air, promoting differentiation into a mucociliary phenotype characteristic of human respiratory tract pseudostratified epithelium. The ALI culture system is used for studying respiratory epithelium cell biology, modeling respiratory diseases, and studying drug effects.

SARS-CoV-2 HAE-ALI experiments demonstrate this model recapitulates human data: infection kinetics peak between days 4 and 8 in HAE-ALI culture, consistent with human SARS-CoV-2 viral kinetics in the nasal epithelium.[7]Multiple coronaviruses have been tested, with growth kinetics and cellular effects correlating to human experience across seasonal versus pandemic viruses. Both influenza and RSV have been modeled in HAE for testing infectivity and therapeutic efficacy.

Additional preclinical work will include quantitative pharmacology and model-based approaches in conjunction with toxicology information in both human model systems and animal studies to project human starting doses for Phase 1 studies.

Scale-Up Manufacturing

We are working internally and with multiple Contract Manufacturing Organizations (“CMOs”) to develop and scale-up proprietary GMP-compatible manufacturing processes. The efficiency of our IMP^{3}ACT platform enables D-MAV manufacturing readiness faster than conventional processes, reducing costs and accelerating delivery of broad-spectrum drug candidates.

By employing solid phase peptide synthesis in an “All-in-One” manufacturing approach, we optimize assembly of complex peptide-linker-functionalized compounds. We are working with a major peptide manufacturer to scale the process to quantities useful for preclinical development through early-stage clinical trials; we anticipate new intellectual property from this collaboration. Our goal is preclinical manufacturing readiness within significantly shorter timelines than traditional processes, aiming to meet or exceed the 100-day goal for vaccine manufacturing-moving from initial natural peptide ligand to drug lead in a single quarter.

Formulation Flexibility

Traditionally peptides as drugs have suffered from very low bioavailability, limiting delivery to intravenous or subcutaneous routes. We are exploring multiple self-administered routes including:

- Intranasal, including nose-to-brain delivery;
- Inhaled/pulmonary delivery (local and systemic applications);
- Subcutaneous patches for extended systemic release; and
- Oral.

We are engineering D-MAVS to possess physicochemical and pharmaceutical properties enabling each delivery route, including solubility, chemical stability, protease resistance, and excipient compatibility. Results indicate our peptide conjugates can be formulated into both liquid and dry powder dosage forms that are room temperature stable and suitable for various delivery devices.

Competitive Strengths of the IMP^{3}ACT *Platform*

We believe the IMP^{3}ACT platform has several key advantages compared to other drug-discovery approaches:

- **Proprietary Data**: Continuing to run our Design-Build-Test-Learn loop results in an expanding proprietary data set giving the IMP^{3}ACT platform a differentiated, difficult-to-duplicate capability to design novel therapeutic candidates against α-helical targets in viruses.
- **Faster & Lower Cost Discovery**: Our ML/AI engine applies computational tools to model structures, energy costs, binding affinities and specificity, protease resistance, and manufacturability to design lead-quality molecules in a fraction of the time, making significantly fewer candidate molecules than required in traditional drug discovery methods.
- **Streamlined & Repeatable Manufacturing**: We are working to scale-up the “All-in-one” manufacturing process to repeatably utilize the same CMC processes for each new drug candidate. We have applied for the FDA Emerging Technology program based on the Food and Drug Omnibus Reform Act of 2022. Our goal is to manufacture 30g of active pharmaceutical ingredient (“API”) of a new therapeutic candidate-typically enough through preclinical activities-in 30 days.
- **Low Commercial Cost of Goods**: Our manufacturing process is fully chemically synthetic and runs on standard peptide synthesis machinery, avoiding the bioprocess and regulatory complexities of recombinant biological processes. We expect very low COGS at commercial scale-for example, targeting total COGS of less than $1/dose in our lead pan-Coronavirus inhibitor program.
- **Flexible Formulation**: We intend to formulate peptide-conjugate therapeutics in a variety of self-administered formats, including nasal and oral inhalation and extended-release dermal patches, optimizing delivery route for indication and market.
- **Increased Probability of Success**: Multi-parameter optimization from the beginning of design and discovery should help avoid “dead-ends” which result in expensive, time-consuming drug development failures.

Drug Development Programs

Through our IMP^{3}ACT platform, we aim to create a diverse and expanding development portfolio of antiviral and GPCR-targeted peptide conjugates. Our initial programs are outlined below.

Pan-Coronavirus Prophylactic for Immunocompromised Patients

We are developing this program for prophylactic prevention of SARS-CoV-2 infection in immunocompromised patients, currently in late lead optimization stage. This program is supported through IND-enabling studies by grants from the Gates Foundation and Blue Knight Program totaling $6.5 million. We intend to seek additional non-dilutive funding through Phase 2a proof-of-concept (antiviral challenge) studies and a development partner.

The SARS-CoV-2 pandemic demonstrated that vaccines and antiviral therapeutics are complementary tools. Rapid COVID-19 vaccine development saved millions of lives. However, continued SARS-CoV-2 immune escape variant evolution, growing 'vaccine hesitancy,' and immune-suppressed sub-groups at risk regardless of vaccination status are treatment gaps only antiviral therapeutics can fill.

Our target product profile for this program, developed in conjunction with the Gates Foundation, is:

- Prevention of infection by all SARS-CoV-2 variants and other human infecting coronaviruses including MERS-CoV;
- Convenient self-administration via intranasal spray;
- Over 8 hours of protection from a single dose; and
- Cost of goods of less than $1 per dose.

We have demonstrated through in vitro pseudotype, live virus, HAE assays and in vivo Syrian hamster models that multiple D-MAVs inhibit viral infection and demonstrate multifold decrease in viral infectious particles when delivered before (pre-exposure prophylaxis or PrEP) or after (post exposure prophylaxis or PEP) viral challenge. DCOY101 and its analogs have demonstrated infection inhibition in cell-based assays against all major SARS-CoV-2 variants of concern and other human-infecting coronaviruses, including SARS-CoV-1, Middle Eastern Respiratory Syndrome ("MERS"), and the "cold-causing" coronaviruses OC43 and NL63, as expected due to strong similarity of fusion region structure across coronaviruses.

The initial indication will be PrEP and PEP prevention of COVID-19 in immunocompromised patients. The Company plans to file an IND application with the FDA or the European equivalent CTA during the first half of 2027, then initiate a Phase I clinical trial in adult healthy volunteers followed by a proof-of-concept Phase 2a human "challenge" study in which healthy volunteers are infected with SARS-CoV-2 under controlled conditions[8]. We expect to partner this program after demonstrating human proof-of-concept.

Immunocompromised Populations

SARS-CoV-2 initially infects ciliated cells in the nasopharynx; most people have mild to moderate illness with viral replication restricted to the upper airways. However, COVID-19 can progress to life-threatening pneumonia in people with predispositions including hypertension, heart failure, cardiac arrhythmia, diabetes, kidney failure, chronic pulmonary disease, old age, and/or compromised immune systems. Severe illness typically begins one week after symptom onset, potentially leading to Acute Respiratory Distress Syndrome (ARDS). COVID-19 can also lead to disease beyond the respiratory tract, including gastrointestinal, acute cardiac, kidney, and liver injury. COVID-19 can lead to Long COVID (Post COVID Condition or "PCC"), a multisystemic condition persisting for weeks to years. The

risk of Long COVID increases with each infection; approximately 6% of symptomatic infections resulted in PCC despite vaccination.[9]

Immunocompromised patients face several distinct challenges:

- Patients post-hematopoietic stem cell transplants or CAR-T therapy are at higher risk of severe COVID-19 within 100 days of treatment, even with rigorous infection control and social avoidance practices.
- Patients with cancer have an impaired immune response to COVID-19 vaccination and are thus at significant risk from SARS-CoV-2 infection.
- Prolonged SARS-CoV-2 infection has been observed in patients with lymphoid or hematological malignancies.
- COVID-19 infections may lead to disruptions of care, for example an interruption in cancer treatment or a delay in a transplant procedure, that can have significant life-altering consequences for patients.

Chronic, persistent SARS-CoV-2 infections in immunocompromised patients are also of public health concern, as continued viral evolution within these patients may be a key source of novel variants of concern.

SARS-CoV-2 Burden of Disease Post-Pandemic

SARS-CoV-2 continues to cause significant morbidity and mortality. Between September 2023 and March 2024, approximately 561,000 people were hospitalized in the U.S. from COVID-19, resulting in approximately 42,000 deaths.[10] By comparison, during the 2023-2024 flu season, there were 470,000 influenza-associated hospitalizations and 28,000 deaths. This suggests COVID-19 prevalence may equal or exceed influenza for the foreseeable future.

Current Treatment Landscape and Opportunity

We are not aware of any antiviral that can prevent SARS-CoV-2 infection. The prophylactic monoclonal antibody Pemivibart was recently authorized under emergency use for immunocompromised patients, but given continued SARS-CoV-2 evolution, it is unclear how long this antibody will remain effective.

Therefore, immunocompromised patients, including those facing transplants or cancer treatments, are at particularly high risk of significant morbidity and mortality upon infection with few options. There is a clear unmet medical need for additional safe, novel prophylactic treatments that can act across multiple SARS-CoV-2 variants.

Our Solution - a pan-Coronavirus D-MAV

We are designing and synthesizing α-helical peptides simultaneously optimized for binding affinity, broad activity against human coronaviruses, potency in cell-based antiviral assays, physicochemical features important for pharmacokinetic durability, formulation, and manufacturability. These peptides are linked via a PEG-based linker to a cholesterol molecule, demonstrated in scientific literature to significantly improve peptide conjugate pharmacokinetic properties.

Mechanism of Action

Viral fusion is required for enveloped viruses to enter human host cells and initiate viral replication. Without fusion, infection will not occur. Treatment with a fusion inhibitor interrupts the infectious cycle, decreasing viral replication. Our pan-Coronavirus peptide conjugates recognize the HRN helical region of the coronavirus spike protein and bind to it, precluding natural binding of spike HRC to HRN and preventing fusion and viral entry.

The basic viral fusion “machinery” structure is highly conserved across enveloped viruses, comprising 11 viral families and 250+ human-infecting viruses[11], presenting opportunity to apply fusion inhibition to other viruses and viral families.

Summary of Proof-of-Concept Preclinical Data

In vitro cell-based assays:

We demonstrated that a single D-MAV targeting fusion machinery can inhibit viral infection for multiple SARS-CoV-2 variants in pseudotype and live virus infection assays. We have also shown activity against 5/6 other human-infecting coronaviruses: SARS-CoV-1, MERS, OC43, NL63, and 229E. The final human-infecting coronavirus, HKU1, is difficult to culture in vitro and so has not been tested to date.

Figure 1: In Vitro Antiviral Activity of pan-Coronavirus Peptide Conjugates

		Pseudotype Assay IC50 (μM)			Live Virus Assay IC50 (μM)		
	S2 Hom.	DCOY101	DCOY102	DCOY103	DCOY101	DCOY102	DCOY103
WT (D614G)	100%	0.027	0.027	0.052	0.096	0.184	0.124
Alpha	100%	0.015	0.020	0.033			
Gamma	100%	0.029	0.035	0.087			
Delta	100%	0.020	0.031	0.054	0.035	0.106	0.085
P1	100%				0.025	0.013	0.022
Beta	100%	0.017	0.036	0.103			
BA.1	100%	0.021	0.024	0.042	0.022	0.012	0.019
BA.2	100%	0.017	0.021	0.054			
SARS-CoV-1	100%				0.0009	0.000004	0.00007
MERS	54.9%				0.103	0.468	0.246
OC43	51.6%				0.079	0.035	0.048
NL63	21.9%				0.126	0.367	0.233
229E	26.6%				>1.000	1.29	1.51
Zoonotic Threats	100%	TBD (BatWIV1, BatRs3367, BatRsSCH014, BatCoVZXC21, Bat RaTG13, Pan-CoV-GD)					

Human Airway Epithelial Model:

The HAE-ALI system is a HAE cell culture grown at an air-liquid interface (“ALI”), designed to mimic human airway epithelium more closely than traditional submerged cell cultures. In the ALI setup, the basal surface of the human airway (nasal, bronchial, or alveolar) cells is in contact with a liquid culture medium, while the apical surface is exposed to air. This configuration supports cellular differentiation into a mucociliary phenotype characteristic of human respiratory tract pseudostratified epithelium. The ALI culture system is physiologically relevant for studying respiratory epithelium, modeling respiratory diseases, and studying drug efficacy.

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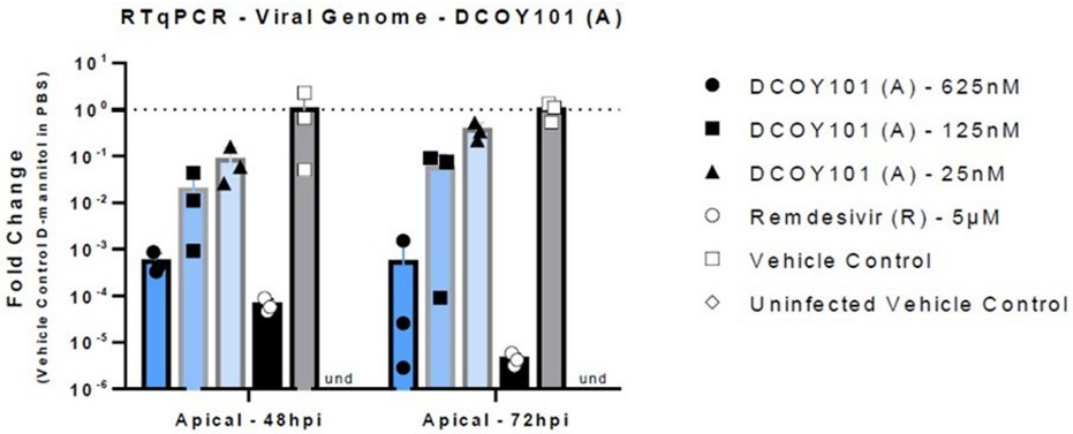
[10] https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_weeklyhospitaladmissions100k_00
[11] https://en.wikipedia.org/wiki/Viral_envelope

DCOY101 D-MAV Inhibits Infection in a Human SARS-CoV-2 HAE-ALI Infection Model:

DCOY101 prevented infection in the HAE model with dose response across 25 nM, 125 nM, and 625 nM. The compound was delivered apically at the same time as viral challenge (prophylactic treatment). DCOY101 demonstrated a dose-dependent decrease in viral load at 48 and 72 hours post-infection, reducing viral load by ~4 logs compared to vehicle. Remdesivir was used as a positive control, demonstrating significant inhibition as expected based on previous prophylactic HAE-ALI results[1], though delivered basolaterally at an 8x higher dose than DCOY101.

Figure 2: Activity of DCOY101 in the Human Airway Epithelial Model



The dose-responsive antiviral efficacy shown in the above graph is due to DCOY101's anti-fusion mechanism, not cellular toxicity. Toxic effects were measured with five different endpoint assays showing no impact on cellular junctions/epithelial layer integrity, no lactate dehydrogenase increase, no inflammatory response induction, and no mucociliary clearance impact after treatment with DCOY101.

In vivo Efficacy Evaluations:

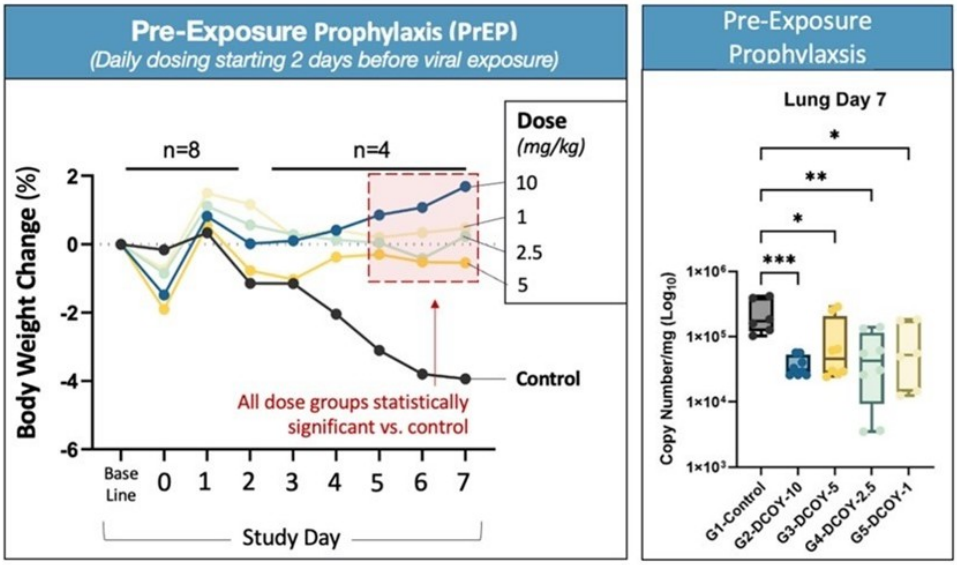
Administration of DCOY101+ reduced pathological body weight loss and decreased viral infectious genomes and live virus particles in vivo in intranasal prophylactic (dosing before viral exposure) and post-exposure prophylactic (dosing after exposure but before symptoms) Syrian hamster models of SARS-CoV-2 delta variant infection.

Syrian Golden hamsters are susceptible to SARS-CoV-2 infection and will become sick, though typically clearing infection by day 7. SARS-CoV-2 infects the hamster nose and causes lung lesions by day 4. Hamsters lose weight, thought to be equivalent to human symptoms.

In the first study (Pre-Exposure Prophylaxis or PrEP), hamsters were dosed intranasally at different dose levels once daily, starting two days before viral challenge and continuing until day 7. By day 7, vehicle-treated animals lost 5-10% body weight as they stopped eating due to illness. Animals treated with DCOY101 maintained or gained weight at the highest dose level, indicating protection from viral effects. Viral load showed significant reduction at all dose levels tested, measured by RT-qPCR on a log scale.

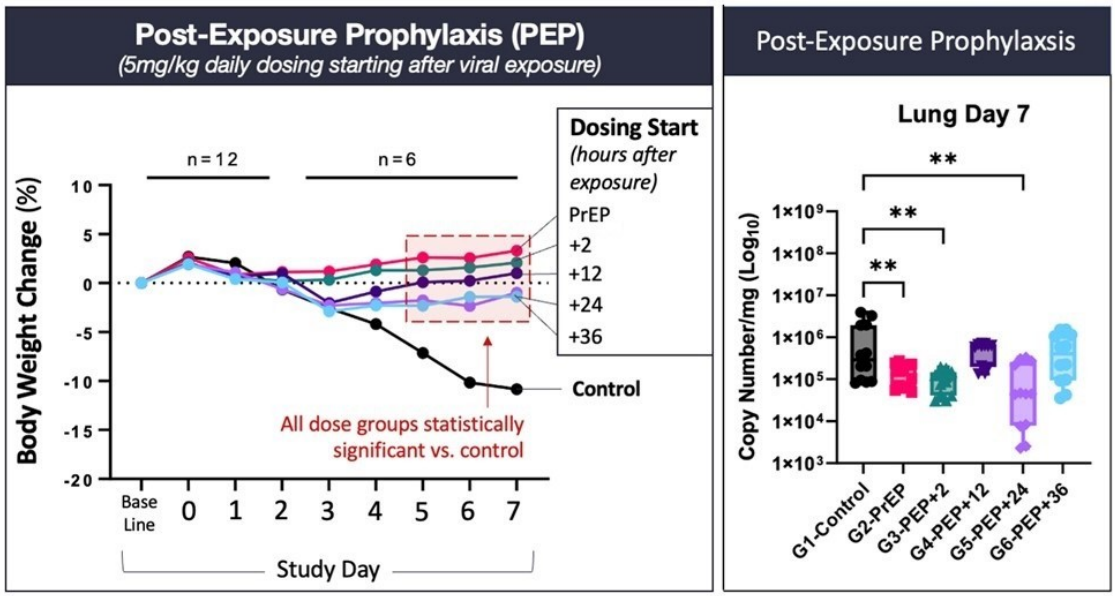
[1] Antiviral Research (2021) 192:105122.

Figure 3: DCOY101 Prevents SARS-CoV-2 Infection in the PrEP Syrian Hamster Model



In the second study (PEP), hamsters were dosed intranasally beginning at various timepoints after viral challenge (2, 12, 24, and 36 hours post-challenge). Control animals began losing weight between 24 and 48 hours. Animals treated with DCOY101 maintained weight throughout the study across all timepoints tested, even when dosing started 36 hours after virus-within the symptomatic timeframe. This result suggests our pan-Coronavirus intranasal D-MAV could also have therapeutic activity.

Figure 4: DCOY101 Prevents SARS-CoV-2 Infection up to 36 hours Post Exposure



Preclinical Research Plans

We have demonstrated in vitro activity across human-infecting coronaviruses with significant antiviral activity. SARS-CoV-2 infection can be significantly inhibited with prophylactic DCOY101 treatment in the human organoid HAE-ALI model and in vivo in pre-exposure and PEP hamster models.

Lead Optimization:

The IMP^{3}ACT Platform acts as an iterative feedback loop incorporating data from in vitro experiments to improve candidate peptide design. Typical data includes SPR binding potency, cell-based activity via pseudotype or live virus assays, and molecular parameters. By incorporating experimental data, more potent and drug-like peptide binders can be designed with multiple parameter optimization simultaneously. This ML/AI-enhanced design approach reduces combinatorial research costs and allows lower-cost manufacturing due to improvements in synthesis speed and scale. The platform achieves manufacturing readiness within significantly shorter timelines, aiming to meet or exceed a 100-day goal for vaccine manufacture.

Use of Physiologically Relevant Human Tissue Models:

The HAE model uses primary differentiated human biopsy tissue with appropriate architecture and cellular complexity, allowing infections from standard respiratory viruses including RSV, SARS-CoV-2, and influenza.[1] SARS-CoV-2 replication kinetics in HAE-ALI cultures is similar to that observed in humans. We believe this human-based model will be useful to optimize pharmacokinetic properties, with human nasal tissue providing the most predictive tool versus rodent models. This medium-throughput system allows careful evaluation of tissue residence time and formulation excipient effects.

CMC

Drug Substance: Continuous Manufacturing - IMP^{3}ACT *Platform:*

We use a proprietary patent pending manufacturing technology which, by thoughtful design and differentiation of chemically active sites, allows complete manufacture of the target compound from beginning to end without intermediate isolation or purification. Both the peptide component and the final cholesterol linker/anchor are assembled in one continuous operation, with the compound isolated only after the target is fully assembled.

The advantages of the continuous manufacturing process are several:

1. A single continuous operation to produce a very complex molecule.

2. Overall improvement of synthesis speed

- Continuous manufacturing process time to final product is approximately 5-6 days, versus approximately 8 weeks for similar compounds requiring numerous isolations and purifications.

3. In-process analytical and quality checks can be performed to check on progress of the assembly of the target molecule.

- High quality of process output is assured by continuous monitoring of combined unit operations.

4. Simplicity of overall process.

- Instead of as many as roughly 70-unit operations and numerous purifications, this continuous process requires only material inputs and a single isolation and purification.

Drug Substance: Distributed Manufacturing - IMP^{3}ACT *platform*

We project that IMP^{3}ACT, described above, can become a modular, distributed manufacturing platform if the following process development criteria are met:

1. Experience with multiple product manufactures enables continuous processing from start to finish to be optimized to maximize yield and purity of the final product.

2. This experience leads to an understanding of the critical process parameters, variables and attributes affecting product quality which can be applied to efficient continuous processing.

3. Robust and predictive in-process controls are developed.

4. Process concentrations are high.

5. Final purification and isolation of the agent produced can be made efficient and robust; and

6. The above criteria having been met, modular, portable standalone manufacturing skids with modest utility requirements are assembled and shown to be viable for the process.

This type of modular, distributed manufacturing has been demonstrated for vaccine production “in-country” where the vaccines are urgently required. We propose developing a similar modular, portable continuous manufacturing platform for use “in-country” where viral outbreaks occur. We intend this process to be straightforward enough that deep chemical processing knowledge is not required to produce needed medicines.

Drug Product

For drug product development, we are developing and optimizing multiple nasal candidate formulations containing our D-MAVs, including liquid and dry powder. We have demonstrated suitability of our peptide conjugates in shelf-stable aqueous nasal formulations containing typical pharmaceutical excipients and identified multiple lead formulation candidates. We have demonstrated delivery at therapeutic doses via conventional nasal spray devices such as the VP7 Spray Pump and Unidose Liquid Nasal Spray devices from Aptar Pharma Inc. (“Aptar”). We are also developing dry powder formulations for nasal delivery via the Unidose Powder Nasal Spray device available from Aptar.

Clinical Development Plan

We expect to file an IND application with the FDA or the European equivalent CTA for our optimized pan-Coronavirus peptide conjugate within the first half of 2027 and initiate a Phase 1 trial shortly thereafter. Our planned Phase 1 trial is expected to be randomized, placebo-controlled with single ascending daily intranasal dose and multiple ascending dose in up to 40 healthy volunteers (part A), followed by a 12-healthy volunteer cohort given daily intranasal dose for 28 days (part B).

Primary endpoints are expected to determine safety and tolerability of the optimized clinical candidate administered daily as an intranasal spray. Secondary endpoints will include evaluation of pharmacokinetic profiles in the nose and oropharyngeal cavity over 12 hours, device delivery characterization, mucociliary clearance, and nasal residence time.

We anticipate taking two dose levels into a Phase 2 proof-of-concept human challenge trial with up to 250 healthy volunteers, who are administered SARS-CoV-2 under carefully controlled and monitored conditions to establish the PK/efficacy relationship and proof of concept.

Other Indications for our pan-Coronavirus Antiviral

We believe there may be opportunities to develop DCOY101+ in additional indications, including:

- **Inhaled COVID-19 Therapeutic**: DCOY101 has demonstrated activity in hamsters against SARS-CoV-2 infection even when administered up to 36 hours after viral challenge, when significant symptoms have emerged. DCOY101+ may have utility as a COVID-19 treatment alternative to Paxlovid with a significantly superior DDI profile, benefiting immunocompromised, high-risk, and elderly patients already taking drugs contraindicated to Paxlovid.

- **Middle Eastern Respiratory Syndrome ("MERS") Therapeutic**: DCOY101+ has shown activity against MERS-CoV coronavirus in live virus cell-based assays. MERS symptoms range from mild respiratory illness to severe disease with approximately 35% case fatality rate-much higher than SARS-CoV-2.

- **Broad Respiratory Antiviral (Flu/COVID-19/RSV)**: Influenza, RSV, and SARS-CoV-2 continue to pose significant global health threats. There is urgent need for potent, versatile antiviral agents targeting multiple viral strains. A single peptide-conjugate therapeutic active against major respiratory viruses from these three viral families with an excellent safety profile could fill a significant unmet medical need, particularly in immunocompromised patients and children.

Clinical Rationale and Disease Description

Globally, acute lower respiratory tract infections ("LRTI") are among the top three causes of death and disability in children and adults, causing nearly 4 million deaths annually and leading deaths in children under 5.[2] Viruses are estimated causative in up to 50% of respiratory infections, with influenza, RSV, and coronaviruses identified often.

Current Treatment Landscape and Opportunity

Current medical approaches include vaccination and antiviral treatment where applicable. Vaccination coverage appears to be decreasing globally. Influenza vaccination among healthcare professionals increased during COVID-19 up to ~90% but has since decreased to 81% in 2022-23. By late 2023, only 14% of American adults got the latest SARS-CoV-2 vaccine, despite vaccinated individuals being 54% less likely to get COVID-19. RSV vaccine uptake appears substantially less than flu rates.

Antiviral medications for influenza (Tamiflu, Relenza, Repivab) and COVID-19 (Paxlovid) exist, but influenza drugs are subject to resistance and Paxlovid is underutilized due to DDI concerns. Society's reluctance to maintain vaccinations can have significant public health repercussions, including increased disease burden, outbreak risks, and resistant strain transmission.

Our D-MAV therapeutic that treats LRIs from three major respiratory endemic and epidemic viruses would be unprecedented and could fill a significant medical need given the morbidity and mortality associated with LRIs globally.

Our Solution

We intend to explore combining fusion inhibitory peptides for SARS-CoV-2 (coronaviruses), RSV (paramyxoviruses), and flu (orthomyxoviruses) in a single molecule, investigating several approaches to optimize breadth of activity.

Mechanism of Action

Figure 5: Conservation of the 6-helix bundle across class I fusion proteins from 3 viral families

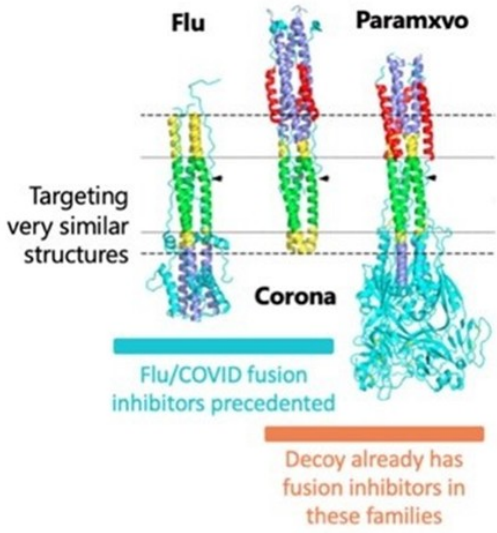


Figure 5 adapted from Igoneta, S. et. al., Proc Natl Acad Sci U S A. 2011 Dec 13;108(50):19967-72. doi: 10.1073/pnas.1108910108.

We target the conserved fusion machinery common to influenza A&B, paramyxoviruses (RSV A&B, hMPV, hPIV, measles), and coronaviruses (SARS-CoV-2, OC43, NL63). We believe a single molecule targeting all three major respiratory viral families is possible, given the highly conserved protein structure of the 6-helix post-fusion bundle common to these viruses as shown in Figure 5. By focusing on this shared mechanism, our project aims to pioneer a versatile D-MAV antiviral agent significantly impacting global health by mitigating the LRTI threat.

Summary of Proof-of-Concept Preclinical Data

Significant progress has been made with our leading antiviral peptide conjugate series, DCOY101+, showing strong in vitro effectiveness against all tested SARS-CoV-2 variants and other human coronaviruses including MERS, SARS-CoV-1, OC43, and NL63 (see Fig. 1, 2). In vivo, DCOY101+ has demonstrated antiviral effects and maintained therapeutic levels for over 8 hours when administered intranasally in Syrian golden hamsters (Figures 3, 4).

Recently, our rapid discovery engine has produced broad-spectrum paramyxovirus inhibitors with promising in vitro proof-of-concept results against RSV-A, RSV-B, and HPIV3 (Fig. 6). Synthesis of these novel D-MAVs was completed in just four days with the “All-in-one” synthesis process.

Figure 6: Activity of our Peptide Conjugate Antivirals Against 3 viruses from the Paramyxovirus Family

A.

	RSV_{A2}			$RSV_{B\ 18537}$		
Compound	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index
TCM353121 (nM)	0.005	>100	>20000	0.03	>100	>3333
DCOY3001	<0.04	5.7	>143	0.04	5.91	148
DCOY3002	0.17	>10	>58.8	0.87	>10	>11.5
DCOY3003	0.2	>10	>50	1.55	>10	>6.45
DCOY3004	0.05	8.46	169	<0.04	>10	>250

B.

	$hPIV_{C243}$		
Compound	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index
Ribivarin (ug/mL)	17.8	>100	>4.57
DCOY3001	6.5	>10	>1.53
DCOY3002	0.5	>10	>20
DCOY3003	0.05	1.89	37.8
DCOY3004	>5.29	5.29	---

DCOY3002: potent activity (< 1 uM) against 3 viruses

On March 26, 2025, we announced that these antiviral drug candidates also showed promising in silico activity against the measles and Nipah viruses based on molecular dynamics modeling. AlphaFold2 multimer predicted that the possibility of expected six helical bundle formation with measles or Nipah HR1 domains is very high. Molecular Dynamics simulations and MMGBSA calculations showed the rationally designed fusion inhibitor can bind to measles or Nipah HR1 domains with similar affinity to the native complex, and approximately the same as its calculated binding energy to hPIV3, RSV A, and RSV B (which have demonstrated in vitro activity with EC50 <1 uM). We believe there is reasonable probability the fusion inhibitor will show similar activity against measles and Nipah in vitro, though this cannot be confirmed until relevant experiments are performed.

We have demonstrated D-MAV with broad-based antiviral POC against two of the three respiratory viral families targeted. Based on in silico tools, we believe it will be possible to design a single molecule also targeting influenza.

Clinical Development Plan

We intend to follow a similar clinical program structure as our pan-Coronavirus prophylactic. Phase 1 would focus on safety and tolerability of an inhaled formulation. Phase 2 would include a healthy volunteer human challenge trial using multiple arms to interrogate all three viral families (flu A, RSV, SARS-CoV-2) to determine PK/efficacy relationship and establish human dose levels and proof of concept.

Potential Future Indications

Upon establishing proof of concept as outlined above, we believe there would be several attractive commercial indications for this candidate, including:

- Therapeutic treatment of early LRTIs in immunocompromised patients via inhaled administration (mortality rates can be as high as 50%[1] in some severely immunocompromised populations);
- Prophylactic use in highly immunocompromised patient populations, including immunocompromised pediatric populations;

- Therapeutic use in large populations that are susceptible to LRTIs, including people who are 65+ or who are suffering from high-risk conditions such as Type II diabetes, chronic kidney disease, congestive heart failure, and chronic obstructive pulmonary disease; and

- Broad use among otherwise healthy populations during seasonal surges in 'influenza-like illness.'

Competitors and Competitive Advantage

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and emphasis on proprietary products. While we believe our technologies, knowledge, experience, and scientific resources provide competitive advantages, we face potential competition from major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Any potential product candidates we successfully develop and commercialize will compete with existing and new therapies.

Our potential competitors include large pharmaceutical and biotechnology companies, as well as specialty and generic or biosimilar drug companies. Many have significantly greater financial and human resources and expertise in R&D, manufacturing, preclinical testing, clinical trials, regulatory approvals, and marketing. Smaller companies may also prove significant competitors through collaborations with established companies. These competitors compete with us in recruiting qualified personnel, establishing clinical trial sites, and acquiring complementary products or technologies.

Each of our pipeline candidates faces a unique but, in our view, favorable competitive landscape because of our emphasis on unique value propositions. Specifically:

- **COVID-19 Prevention & Treatment for Immune-Suppressed Patients:** Despite being four years from the COVID-19 pandemic, there are still limited prophylactic options for people with highly suppressed immune function. mRNA vaccines are less effective for immune-suppressed patients[1]. Vaccine efficacy remains at risk from viral evolution, and uptake continues to decline.[2]Long-lasting antibody prophylactics like Evusheld rapidly became obsolete due to viral evolution,[3] and this is likely for pemivibart. Our therapeutic candidate is effective against all SARS-CoV-2 variants and expected to continue effective based on limited evolution in the targeted genome portion. With convenient administration and no requirement for functional immune system, we believe this therapeutic will deliver a unique solution for highly immune-suppressed patients.

- **Broad Respiratory Antiviral (COVID-19/Flu/RSV):** There is significant competition in each area, both from commercialized drugs and pipeline candidates. While vaccines exist, usage continues to be low. We believe our strategy of treating all three viruses-and potentially additional human Coronaviruses and *Paramyxoviruses* causing influenza-like symptoms-with a single therapeutic will deliver a unique value proposition during seasonal ILI surges. A therapeutic that can safely treat a large percentage of ILI-causing viruses would be uniquely useful for healthcare providers.

Intellectual Property

We strive to protect our proprietary technology, inventions, improvements, platforms, program candidates, therapeutic candidates, methods of use, and manufacturing processes by obtaining, maintaining, defending, and enforcing patent and other intellectual property rights in the United States and foreign jurisdictions. We also rely on trade secrets and confidentiality agreements to protect information and know-how not amenable to, or not appropriate for, patent protection.

Our future commercial success depends in part on our ability to:

- obtain, maintain, enforce and defend patent and other intellectual property rights for our important technology, inventions and know-how; preserve the confidentiality of our trade secrets and other confidential information;
- obtain and maintain licenses to use and exploit intellectual property owned or controlled by third parties;
- operate without infringing, misappropriating or otherwise violating any valid and enforceable patents and other intellectual property rights of third parties; and defend against challenges and assertions by third parties challenging the validity or enforceability of our intellectual property rights, or our rights in our intellectual property, or asserting that the operation of our business infringes, misappropriates or otherwise violates their intellectual property rights.

Our portfolio currently consists of solely owned patents and applications. As of December 31, 2025, our intellectual property portfolio includes six patent families covering compositions of matter, manufacturing, and uses relevant to our business, including 17 granted patents and four pending applications acquired through our January 2022 agreement with DeuteRx, LLC. Additionally, our portfolio contains wholly-owned patents and applications related to our IMP^{3}ACT platform. In the United States, we have two compositions of matter patents and one method of use patent with respect to SP-2577 and related compounds expiring in 2032, owned by the University of Utah Research Foundation and exclusively licensed to us. We also have patents covering the composition of SP-3164 with patent term expiration of January 14, 2034.

Patent Prosecution

A PCT patent application filed under the Patent Cooperation Treaty (“PCT”) is not eligible to become an issued patent until national stage applications are filed in jurisdictions where patent protection is sought, within prescribed timelines (generally 30-32 months). To date, we have filed national stage applications in Australia, Canada, Europe, and New Zealand. If national stage applications are not timely filed, we may lose priority date and patent protection on disclosed inventions.

A provisional patent application is not eligible to become an issued patent. It may serve as a priority filing for non-provisional and/or PCT applications filed within 12 months. If non-provisional or PCT applications are not timely filed, we may lose priority date and patent protection.

While we intend to timely file additional provisional, PCT, national stage, and non-provisional patent applications, we cannot predict whether any will result in issued patents. If we do not successfully obtain patent protection, or if scope is insufficient, we will be unable to prevent others from using our technology or developing competing products and technologies.

Our ability to stop third parties from making, using, selling, or importing our technology, inventions, and improvements depends in part on our success in obtaining, maintaining, defending, and enforcing patent claims covering our technology.

Patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Protection afforded by a patent varies product-by-product, jurisdiction-by-jurisdiction, and depends on many factors including patent type, scope, term adjustments and extensions, available remedies, and validity and enforceability. Patent laws and enforcement outside the U.S. are uncertain and may not protect our rights to the same extent. Changes in patent laws and rules may affect our ability to protect inventions and obtain, maintain, defend, and enforce patent rights.

The patent and intellectual property area in biotechnology is evolving with many risks and uncertainties. Third parties may have blocking patents that could prevent commercializing our platform and therapeutic candidates. Our patent

rights may be challenged, narrowed, circumvented, invalidated, or ruled unenforceable. Third parties may independently develop similar technologies.

Because of the extensive time required for development, testing, and regulatory review, any related patent may expire or remain in force for only a short period following commercialization, reducing any competitive advantage. For additional risks, see “Risk Factors- Risks Related to the *Discovery, Development and Commercialization of Potential Product Candidates*.”

Patent Term

The term of individual patents depends on the jurisdiction. In most jurisdictions where we file, patent term is 20 years from the PCT application filing date or, if no PCT application is filed, the earliest non-provisional application priority date. U.S. patents may be extended or adjusted for FDA compliance delays or USPTO prosecution delays. A patent claiming an NCE or biologic product may be eligible for limited patent term extension under the Hatch-Waxman Act for up to five years beyond normal expiration, but cannot extend the remaining term past 14 years from approval date. Only one patent per approved product is eligible for extension. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions. If and when any therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on issued patents.

We intend to seek patent term adjustments and extensions for issued patents in any jurisdiction where available. However, there is no guarantee that authorities will agree with our assessment of whether such adjustments and extensions should be granted, or their length.

Trade Secrets

In addition to patent protection, we rely on trade secrets, know-how, unpatented technology, and other proprietary information to strengthen our competitive position. We may share trade secrets and proprietary information with third parties assisting in development and manufacturing and may enter collaborations requiring such sharing. We take steps to protect trade secrets, including non-disclosure and invention assignment agreements with employees, consultants, collaborators, contract organizations, and advisors. We also maintain physical security of premises and electronic security of IT systems.

Despite these efforts, third parties may independently develop substantially equivalent information and techniques or gain access to our trade secrets. Non-disclosure and invention assignment agreements may not have been duly executed, and counterparties may breach them. Agreements or security measures may be inadequate, and we may not have adequate remedies for breaches. Disputes may arise regarding rights in inventions arising from work by employees, contractors, or consultants using intellectual property owned by others. For more information, see “Risk Factors- Risks Related to the Discovery, Development and Commercialization of Potential Product Candidates.”

U.S. Patent Term Restoration and Extension and Marketing Exclusivity

In the United States, a patent claiming a new biologic or pharmaceutical product may be eligible for limited patent term extension under the Hatch-Waxman Act, permitting extension of up to five years for patent term lost during development and FDA regulatory review. The restoration period is typically one-half the time between the effective Investigational New Drug ("IND") date and the submission date of New Drug Application ("NDA") or Biologics License Application ("BLA") , plus the time between submission and ultimate approval, except for time when the applicant failed to exercise due diligence. Patent term restoration cannot extend the remaining term past 14 years from approval date. Only one patent per approved product is eligible, and the extension application must be submitted prior to patent expiration. The USPTO reviews and approves extensions in consultation with the FDA.

Marketing exclusivity provisions under the Federal Food, Drug, and Cosmetic Act (the "FDCA") also can delay submission or approval of certain applications. The FDCA provides five-year non-patent marketing exclusivity for an NDA for a New Chemical Entity ("NCE"). During exclusivity, the FDA may not accept an ANDA or 505(b)(2) NDA for another version of such drug, though an application may be submitted after four years with a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement if new clinical investigations essential to approval were conducted-this three-year exclusivity covers only the conditions of use associated with the new clinical investigations. Five-year and three-year exclusivity will not delay submission or approval of a full NDA.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union provides patent term extension through Supplementary Protection Certificates ("SPCs"). An SPC may extend patent term for up to five years after scheduled expiration, providing up to a maximum of fifteen years of marketing exclusivity. In certain circumstances, periods may be extended six additional months for pediatric exclusivity; orphan medicinal products may have a two-year extension of orphan market exclusivity available. SPCs are available throughout the EU, but sponsors must apply country-by-country. Similar patent term extension rights exist in certain other foreign jurisdictions.

We received non-dilutive investments from the Gates Foundation, the Center for the Biologic Advanced Research and Development Authority and Johnson & Johnson through the U.S. Government's Blue Knight Program, with some additional support from the European Union's IMI-CARE Consortium and the Massachusetts Life Sciences Seed Fund.

Machine Learning and Artificial Intelligence computing support: Google AI Startup Program and the NVIDIA Inception Program include computing credits as well as hardware and software discounts.

Sales and Marketing

While we are not a commercial-stage biotechnology company at this time, we believe the structure of our drug development pipeline and emerging pharmaceutical marketing trends could allow efficient implementation of a commercial model addressing high-revenue markets without building a traditional 'big pharma' sales organization.

Small, Specialized Sales Force

Many immune-suppressed, high-risk, or orphan cancer patient groups that would be key early commercial targets are typically served by specialist HCPs in easy-to-identify medical settings. In the United States:

- The great majority of solid organ transplants are performed at one of approximately 250 transplant centers[4]
- Leukemia/Lymphoma patients are typically associated with one of approximately 70 NCI-designated cancer centers[5]

Should pipeline candidates reach commercialization, we believe it will be feasible to build a small, specialized sales force working across our portfolio to target these patient settings in a financially efficient manner, driving revenue while maintaining cost-effective commercial and medical affairs footprints.

Emerging "Telehealth" Commercial Model

We believe we will be well-positioned to implement an innovative commercialization strategy leveraging emerging technologies to optimize patient engagement, HCP access, and product delivery. Key components could include:

- **Digital Patient Engagement:** Leveraging digital channels such as social media and paid search to efficiently educate patients about our products, ensuring broad reach and accessibility.
- **Telehealth Partnerships:** Collaborating with telehealth providers to enable convenient and immediate access to HCPs, complementing direct-to-consumer campaigns and facilitating seamless patient engagement.
- **At-Home Delivery:** Implementing a streamlined process for at-home delivery of our products following prescription, potentially facilitated through telehealth visits, enhancing patient convenience and adherence.
- **Streamlined Distribution:** Aligning with industry trends to establish a streamlined distribution strategy aimed at enhancing efficiency and optimizing gross to net.

Such an innovative commercial model would align with our status as an emerging biotechnology organization and reflect broader industry trends. By integrating these channels, we would orchestrate a streamlined patient journey, reducing time and in-person contact required to access therapies-mitigating infectious disease transmission risks while enhancing operational efficiency and return on investment.

Manufacturing

We do not currently own or operate manufacturing facilities for clinical or commercial quantities of our potential product candidates. We rely, and expect to continue to rely, on third parties for product manufacturing, research, preclinical and clinical testing, and these third parties may not perform satisfactorily or dedicate adequate resources.

Government Regulation and Product Approvals

United States Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, the FDA's implementing regulations, and other federal and state statutes and regulations, govern, among other things, research, development, testing, manufacture, quality control, safety, effectiveness, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. We cannot market a drug product candidate in the United States until the drug has received FDA approval.

The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

Drug Development Process

The process required before a drug may be marketed in the United States generally includes the following:

- completion of extensive non-clinical laboratory tests and animal studies in accordance with the FDA's Good Laboratory Practices (GLP) regulations, applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application (IND) for human clinical testing, which must be deemed effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB) overseeing each clinical site before each trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices (GCP) requirements, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a New Drug Application (NDA) for marketing approval that includes substantial evidence of safety and effectiveness from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate;
- consideration by an FDA Advisory Committee, if applicable;
- satisfactory completion of potential FDA audits of the preclinical study and clinical trial sites that generated the data in support of the NDA;
- satisfactory completion of an FDA pre-approval inspection of the nonclinical, clinical and/or manufacturing sites or facilities at which the active pharmaceutical ingredient, (API), and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices (cGMP); and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States, including agreement on post-marketing commitments, if applicable.

Before testing any drugs with potential therapeutic value in humans, the drug enters the preclinical testing stage. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including GLP and the Animal Welfare Act.

Before commencing the first clinical trial in humans, an IND must be submitted to the FDA, and the IND must become effective. An IND sponsor must submit the results of pre-clinical testing to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin if all other requirements, including IRB review and approval, have been met. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Even after the IND has gone into effect and clinical testing has begun, the FDA may also impose clinical holds on clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the new investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with state and federal regulations, including GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, including stopping rules that ensure a clinical trial will be stopped if certain adverse events (AEs) should occur. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB, for approval of each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their www.clinicaltrials.gov website.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, safety and side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a larger but limited patient population to study metabolism of the drug, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA has expressed statutory authority to require post-market clinical studies to address safety issues.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in vitro testing and other sources that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. 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 limited circumstances, the FDA also permits the administration of investigational drug products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requested physician.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. Additionally, 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.

FDA Review and Approval Process

After completion of the required clinical testing, a sponsor may prepare and submit an NDA to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all non-clinical, clinical and other testing and a compilation of data relating to the product's toxicology, pharmacology, chemistry, manufacture and controls. In addition, under the Pediatric Research Equity Act, as amended, an NDA or supplement to an NDA generally must contain data to assess the safety and effectiveness of the product 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 FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Under the Prescription Drug User Fee Act (PDUFA) performance goals that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA, because the FDA has approximately two months to make a "filing" decision. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to six months of the "filing" date for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Within 60 days following submission of the application, the FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may issue a refuse-to-file letter and request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with additional information. The resubmitted application also is subject to be reviewed before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility(ies) in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for consideration, discussion and a vote on specific questions relevant to the approval decision. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP requirements is satisfactory and the NDA contains data that provides substantial evidence that the drug is safe and effective in the indication studied.

During the NDA review process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure safe use of the product. If the FDA concludes a REMS is needed, the sponsor must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required. A REMS could include a medication guide, communication plan or elements to assure safe use, such as required healthcare provider or pharmacy certification, a patient registry and other safe use conditions. The requirement for a REMS can materially affect the potential market and profitability of the product.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data, or information, in order to resubmit the application for another cycle of FDA review. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the complete response letter, or withdraw the application. If those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post- approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS to ensure that the benefits of the drug outweigh the potential risks. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, FDA determines the risk outweighs the benefits of the product or other problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within 10 months of receipt or 6 months of receipt for priority efficacy supplements.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although there may be some increased communication opportunities, orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a drug candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease

or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

As in the United States, designation as an orphan drug for the treatment of a specific indication in the European Union, must be made before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for development and review of new drug products that meet certain criteria. Specifically, new drug products 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 and the specific indication for which it is being studied. The sponsor of a new drug may request that the FDA designate the drug as a Fast Track product at any time during the clinical development of the product. For a Fast Track-designated product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. Fast Track designation may be rescinded if FDA determines the program no longer meets the qualifying criteria for Fast Track.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug product designated for priority review in an effort to facilitate the review on a six-month, rather than the standard ten-month, timeline. Currently, the Company has no FDA approved products.

Additionally, a product may be eligible for accelerated approval under subpart H if it treats a serious or life-threatening disease or condition, provides meaningful advantage over existing treatments, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit or on an intermediate clinical endpoint. If a product qualifies for accelerated approval, the product may be approved based on an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict the drug's clinical benefit. As a condition of accelerated approval, the FDA will require that a sponsor of a drug product subject to accelerated approval perform an adequate and well-controlled post-marketing clinical trial to confirm clinical benefit. The Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted in December 2022, provided the FDA with streamlined authority to withdraw accelerated approval if a sponsor fails to conduct any required post-approval confirmatory trial with "due diligence", or if such trial fails to verify clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval that promotional materials be submitted in advance of initial dissemination, which could adversely impact the timing of the commercial launch of the product.

In addition, under the provisions of the FDA Safety and Innovation Act (FDASIA), the FDA established the Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug 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 features of Fast Track designation, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is distinct from both accelerated approval and priority review, but these can also be granted to the same product candidate if the relevant criteria are met. The FDA may take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request. Breakthrough Therapy designation may be rescinded if the FDA determines the program no longer meets the qualifying criteria for breakthrough therapy.

Fast Track designation, priority review, accelerated approval and Breakthrough Therapy Designation do not change the standards for approval, but may expedite the development or approval process. Even if we receive Fast Track or Breakthrough designations for our potential product candidates, the FDA may later decide that our potential product candidates no longer meet the conditions for qualification. In addition, these designations may not provide us with a material commercial advantage.

Post-Approval Requirements

Once an NDA is approved, a product is subject to extensive continuing post-approval requirements. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. For example, as a condition of approval of the NDA , the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS or other surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects' entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters, warning letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals; and
- product seizure or detention, or refusal to permit the import or export of products; or injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications 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, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA) and its implementation regulations, as well as the Drug Supply Chain Security Act (DSCSA), which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions.

Some countries outside of the United States have a similar process that requires the submission of a clinical trial application (CTA), much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to a single EU portal for harmonized assessment at EU level with additional ethics review on each country's national level, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, a clinical trial may proceed in that country. To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application (MAA). The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all E.U. member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), established at the European Medicines Agency ("EMA"), is responsible for conducting the initial assessment of a product. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops. The decentralized procedure is available to applicants who wish to market a product in various E.U. member states where such a product has not previously received marketing approval in any E.U. member state.

In the European Union, under the existing framework, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies.

The approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on 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 our net revenue and results.

Outside the United States, pricing of prescription pharmaceuticals is subject to governmental control in many countries. In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other Healthcare Laws

Although we currently do not have any products on the market, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

Such restrictions under applicable federal and state healthcare laws and regulations include, among others: the federal Anti-Kickback Statute, which prohibits persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration to induce or reward referrals for services covered under federal healthcare programs such as Medicare and Medicaid; the federal civil and criminal false claims laws, including the civil False Claims Act, which prohibit knowingly presenting false or fraudulent claims for payment to the federal government; the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which imposes obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and the federal transparency requirements known as the Physician Payments Sunshine Act, which requires certain manufacturers to report annually to the Centers for Medicare

& Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals. Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may also apply to healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. In March 2010, the United States Congress enacted the Affordable Care Act (the "ACA"), which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of potential importance to our potential product candidates are: an annual, non-deductible fee on entities that manufacture or import specified branded prescription drugs and biologic agents; expansion of eligibility criteria for Medicaid programs; expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program; expanded types of entities eligible for the 340B drug discount program; and establishment of the Medicare Part D coverage gap discount program. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law, and we will continue to evaluate the effect that the ACA and any changes thereto could have on our business.

In August 2022, the Inflation Reduction Act of 2022 was signed into law and requires the federal government to negotiate prices for some high-cost drugs covered under Medicare, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries, and caps Medicare beneficiaries' out-of-pocket spending under the Medicare Part D benefit. We will monitor this issue to determine the effects of this legislation on our business.

Facilities

We lease offices in the Texas Medical Center Houston, Texas, under a month-to-month lease. Currently, this facility consists of approximately 300 square feet and accommodates our financial and general administrative activities. We also maintain offices at One Broadway, 14th Floor, Cambridge, MA 02142. Additionally, we lease laboratory space at 45-18 Ct Square W, Long Island City, NY 11101. The Company does not own any physical property, plants, or laboratories.

Employees and Human Capital Resources

As of March 20, 2026, we had eleven full-time employees. We also utilize the services of a similarly sized team of contractors with whom we have ongoing multi-year relationships, and a three-person scientific advisory board consisting of academic clinicians that can be considered key opinion leaders in the therapeutic areas in which we plan to operate. We have never had a work stoppage, and none of our employees are represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

Legal Proceedings

We are not currently a party to any legal proceedings, the outcome of which we believe, if determined adversely to us, would individually or in the aggregate, have a material adverse effect on our business, financial condition, or results of operations. From time to time, we may become involved in legal proceedings arising in the ordinary course of business.

Corporate Information and Web Site Access to SEC Filings

Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.) was incorporated as Flex Pharma, Inc. (“Flex Pharma”), in Delaware in February 2014. In July 2019, the Company’s wholly owned subsidiary, Falcon Acquisition Sub, LLC, merged with and into Salarius Pharmaceuticals, LLC (“Private Salarius”), with Private Salarius becoming the Company’s wholly owned subsidiary, and the Company changed its name to Salarius Pharmaceuticals, Inc. On November 12, 2025, pursuant to the Merger Agreement, MergerSub I merged with and into Legacy Decoy, and immediately thereafter Legacy Decoy merged with and into MergerSub II, resulting in the Legacy Decoy business becoming a wholly owned subsidiary of the Company. On January 8, 2026, the Company changed its legal name from “Salarius Pharmaceuticals, Inc.” to “Decoy Therapeutics Inc.” by filing a Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The Company’s principal executive offices are located at 2450 Holcombe Blvd., Suite X, Houston, Texas 77021 and its telephone number is (713) 913-5608. The Company’s website address is www.decoytx.com.

Information on this website is not a part of this Form 10-K. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 ("Exchange Act") are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

[1] https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(23)00142-6/fulltext
[2] https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults.html
[3] https://www.cnbc.com/2023/01/27/covid-fda-pulls-evusheld-because-its-not-effective-against-subvariants.html
[4] https://optn.transplant.hrsa.gov/about/search-membership/
[5] https://www.cancer.gov/research/infrastructure/cancer-centers

Item 1A. Risk Factors

The risk factors described below, as well as statements described elsewhere in this Annual Report on Form 10-K, including our audited Consolidated Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Conditions and Results of Operations", or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition, and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations.

Risks Related to our Business

Nasdaq may delist our securities from trading on its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Currently, our common stock is publicly traded on The Nasdaq Capital Market. On December 31, 2025, we received a delisting determination from Nasdaq because the closing bid price of our common stock was below the $1.00 minimum requirement for 30 consecutive business days. Because we previously effected the 2025 Reverse Stock Split and remain subject to a mandatory panel monitor, we were not eligible for a 180-day grace period. On March 13, 2026, the Company received a written notice from the Hearings Panel notifying the Company that it has been granted until March 20, 2026 to regain compliance with the Minimum Bid Price Requirement.. Additionally, Pursuant to the Hearings Panel's decision, the continued listing of the Company's securities is subject to the condition that the Company must demonstrate compliance with the Minimum Bid Price Requirement on or before March 20, 2026.

On January 17, 2025, Nasdaq notified us that the Merger constitutes a business combination that will result in a "Change of Control" pursuant to Listing Rule 5110(a) in connection with step two of the transaction and, accordingly, we will be required to satisfy all of Nasdaq's initial listing criteria and to complete Nasdaq's initial listing process, including the payment of all applicable fees. We must complete the process prior to our stockholder approval for the issuance of 20% or more of our pre-transaction shares in connection with the conversion of the preferred shares issued at the closing of the merger into shares of our common stock.

We may never meet the Nasdaq initial listing standards and we do not intend to submit the initial listing application and call the special meeting of stockholders to approve the conversion of the Preferred Stock into common stock until we expect to be able to meet the initial listing standards. If we fail to regain compliance through the Hearings Panel process or fail to meet the initial listing requirements following the Merger, Nasdaq will delist our securities.

We cannot assure you that we will be able to regain compliance or meet those initial listing requirements. Even if our securities are so listed, we may be unable to maintain the listing of our securities in the future. We are subject to Mandatory Panel Monitor for a period of one year from the date of each respective Hearings Panel letter. As we have been found out of compliance with the Minimum Bid Price Requirement during this monitoring period, we are currently subject to the delisting procedures described above. In order to continue listing our securities on Nasdaq following the Merger, we will be required to maintain certain financial, distribution and stock price levels. If Nasdaq delists our securities from trading on its exchange and we are not able to list our securities on another national securities exchange or regain compliance with Nasdaq, our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts states from regulating the sale of certain securities, which are referred to as "covered securities." Since our common stock is listed on Nasdaq, it is a covered security. Although states are preempted from regulating the sale of covered securities, the federal statute does allow states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then states can regulate or bar the sale of covered securities in a particular case. If we were no longer listed on Nasdaq, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

Our financial condition raises substantial doubt regarding our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Based on our current operations and operating plans, however, we believe that our existing cash and cash equivalents will not be sufficient to fund our operating expenses and capital expenditure requirements for the next 12 months. Included in our anticipated future capital needs will be capital for advancing our research and development activities including our goal to begin a Phase 1 clinical trial for DCOY-101 potentially in the first half of 2027. As a result, we have determined that there is substantial doubt regarding our ability to continue as a going concern, and our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2025, an explanatory paragraph about such substantial doubt regarding our ability to continue as a going concern.

The substantial doubt regarding our ability to continue as a going concern may adversely affect our stock price and our ability to raise capital necessary to execute our current operating plans. If we are unable to obtain additional capital, we may not be able to continue its operations on the scope or scale as currently conducted, and we could be forced to cease operations, in which case you could lose all or most of your investment.

We have never generated revenue from product sales and all of our potential product candidates are currently in the pre-clinical stage, and we may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.

We are a preclinical biopharmaceutical discovery and development company. We plan to bring certain potential product candidates into the early stages of clinical development beginning in the first half of 2027, however, our ability to do so will depend on factors beyond our control, including our ability to raise capital and to effectively navigate the regulatory requirements, particularly those imposed by the FDA which are described elsewhere in these Risk Factors. Because of the need to proceed to and complete clinical trials, establish safety and efficacy and obtain regulatory approval, which is an expensive and time-consuming process, we do not anticipate generating revenue from product sales for at least several years and will continue to sustain considerable losses during that time. We may develop a partnership that could generate income sooner, but there is no guarantee that will be achievable.

Because we have yet to generate revenue from product sales on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our prospects and the likelihood of success or failure of our business.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical potential product candidates. We have no pharmaceutical potential product candidates that have proceeded to clinical trials or generated any commercial revenue, do not expect to generate revenues from the commercial sale of pharmaceutical products for the foreseeable future, and may never generate revenues from the

sale of pharmaceutical products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

- identifying and validating new therapeutic strategies;
- entering into and maintaining collaborations and relationships with large pharmaceutical or biotechnology companies;
- completing our research and preclinical development of pharmaceutical potential product candidates;
- initiating and completing clinical trials for pharmaceutical potential product candidates;
- seeking and obtaining regulatory marketing approvals for pharmaceutical potential product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical potential product candidates for which we obtain regulatory marketing approval with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we cannot predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by regulatory agencies to perform additional unanticipated studies and trials.

Even if one or more pharmaceutical potential product candidates we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved pharmaceutical product candidate. Moreover, even if we can generate revenues from the sale of any approved pharmaceutical products, we may not become profitable and may need to obtain additional funding to continue operations.

Because early-stage drug development requires major capital investment, as we continue to incur operating losses, we will need to raise additional capital or form strategic partnerships to support our research and development activities in the future.

We are still in the early stages of development of our potential product candidates, and have no products approved for commercial sale or presently in clinical trials. Our ability to proceed to and conduct clinical trials in a cost-effective manner and within the desired time frames remains subject to uncertainties including the potential for supply chain shortages and difficulties in obtaining adequate participant enrollments which are common challenges faced in conducting clinical trials. Further, developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as potential product candidates are advanced toward clinical programs. If we are able to advance our products to and through clinical trials, we may need to raise additional capital to support our operations and/or form partnerships, in addition to our existing collaborative alliances, which may give substantial rights to a partner. Such funding or partnerships may not be available to us on acceptable terms, or at all. Moreover, any future financing may be very dilutive to our existing stockholders.

As we move lead compounds through toxicology and other preclinical studies, also referred to as nonclinical studies, we have and will be required to file an IND or its equivalent in foreign countries, and as we conduct clinical development of potential product candidates, we may have adverse results that may cause us to consume additional capital. Our partners may not elect to pursue the development and commercialization of our potential product candidates subject to our respective agreements with them. These events may increase our development costs more than we expect. We may need to raise additional capital or otherwise obtain funding through strategic alliances if we initiate clinical trials

for new potential product candidates other than programs currently partnered. We will require additional capital to obtain regulatory approval for, and to commercialize, potential product candidates.

In securing additional financing, such additional fundraising efforts may divert our management's attention from our day-to-day activities, which may adversely affect our ability to develop and commercialize potential product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we cannot raise additional capital when required or on acceptable terms, we may be required to:

- accept terms that restrict our ability to issue securities, incur indebtedness, or otherwise raise capital in the future, or restrict our ability to pay dividends or engage in acquisitions;
- significantly delay, scale back or discontinue the development or commercialization of any potential product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any potential product candidates we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects or may render us unable to continue operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or shareholder derivative litigation often followed certain significant business transactions, such as the sale of a business division or announcement of a merger. We may become involved in this type of litigation in the future. Litigation is often expensive and diverts management's attention and resources, which could adversely affect our business.

Risks Related to the Discovery, Development and Commercialization of Potential Product Candidates

If any strategic alliances on which we depend are unsuccessful or are terminated, we may be unable to develop or commercialize certain potential product candidates and we may be unable to generate revenues from our development programs.

We will likely need to use third-party alliance partners for financial, scientific, manufacturing, marketing and sales resources for the development and commercialization of our potential product candidates. We also presently rely on a number of third party vendors for a variety of operational functions, including the provision of our technology infrastructure and other elements of our product candidate development programs as well as critical data storage and processing functions. These strategic alliances, if we are able to enter into, foster and maintain them, will likely constrain our control over development and commercialization of our potential product candidates, especially once a candidate has reached the stage of clinical development. Our ability to recognize revenues from successful strategic alliances may be impaired by several factors including a partner shifting its priorities and resources away from us, failing to perform under required standards or contractual terms, terminating the relationship with us, entering into a dispute or litigation with us or third parties or ceasing operations.

For example, we rely and expect to continue to rely on third parties to conduct some aspects of our preclinical testing and on third-party CROs to conduct clinical trials. This reliance can materially delay our research and development efforts, and increase the costs of undertaking them. Further, any disputes that may arise from our arrangements with CROs or contract manufacturing organizations ("CMOs") may result in additional unexpected expenses and force our management to allocate their limited time to seeking a resolution to the problem, which could materially adversely affect our operations.

Additionally, our reliance on third-party manufacturers to develop products and our anticipated reliance on third-party manufacturers to produce products we may develop in the future entail risks to which we would not be subject if we supplied the materials needed to develop and manufacture our potential product candidates ourselves, including supply chain shortages, the inability to meet any product specifications and quality requirements consistently, a delay or inability to procure or expand sufficient manufacturing capacity, and a failure to comply with current "cGMP" and similar foreign standards. These events could lead to clinical study delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for regulatory actions, including injunction, recall, seizure or total or partial suspension of production.

Termination of or other adverse development with respect to a strategic alliance may require us to seek out and establish alternative strategic alliances with third-party partners. This may not be possible, including due to restrictions under the terms of our collaborations, or we may not be able to do so on terms acceptable to us. If we fail to establish alternative strategic alliances with third-party partners on terms acceptable to us, or at all, we may be required to limit the size or scope of one or more of our programs or decrease our expenditures and seek additional funding by other means. Such events would likely have a material adverse effect on our results of operations and financial condition.

Since we expect to rely on third parties to conduct, supervise and monitor any future clinical trials, if those third parties fail to perform in a satisfactory manner and one that meets applicable regulatory, scientific and safety requirements, it may materially harm our business.

If and when we are able to proceed to clinical trial for a product candidate, we will rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. We anticipate that we or our partners will have limited influence over their actual performance. Nevertheless, we or our partners will be responsible for ensuring that each of our clinical trials is conducted in accordance with our protocol, and that all legal, regulatory and scientific standards are met. Our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, our partners and our CROs must comply with current Good Clinical Practices ("cGCPs"), as defined by the FDA and the International Conference on Harmonization, for conducting, recording and reporting the results of IND-enabling preclinical studies and clinical trials, to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we or our CROs fail to comply with cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulators may require us to perform additional clinical trials before approving any marketing applications. Our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. If our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, fail to recruit properly qualified patients or fail to properly record or maintain patient data, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our contracted CROs will not be our employees, and we cannot control whether they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to failing to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not obtain regulatory approval for, or successfully commercialize our potential product candidates. Our financial results and the commercial prospects for such products and any potential product candidates we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also expect to rely on other third parties to store and distribute drug products for any clinical trials we may conduct. Any performance failure by our distributors could delay clinical development or marketing approval of our potential product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

Because the approach we are taking to discover and develop drugs is novel, including the usage of AI, it may never lead to marketable products.

We are concentrating our therapeutic product research and development efforts on using our proprietary technology, and our future success depends on the continued successful development of this technology and the products derived from it. We have never commercialized any products. The scientific discoveries that form the basis for our efforts to discover and develop drug potential product candidates are relatively new and unproven. The scientific evidence to support the feasibility of developing potential product candidates based on our approach is limited. If we do not successfully develop and commercialize drug potential product candidates based upon our technological approach, we may not become profitable and the value of our stock may decline.

Further, our approach to drug development involves the use of artificial intelligence ("AI") and computing software to identify potential molecules for further research and development processes. The use of AI is relatively novel, and the underlying technology continues to experience substantial changes with the passage of time and as considerable resources continue to be deployed in the market. We are therefore subject to unique risks and uncertainties based on our reliance on and involvement in AI for our operations, including the risk of regulatory developments that may adversely affect or hinder our ability to use this technology or expose us to potential liability arising from such use, the risk that competitors develop or deploy similar or superior systems in their operations that give them an advantage over us, and the risk that the third parties on which we rely for our technology and infrastructure fail to perform as needed or fail to protect our rights, technology, data and interests. Further, we rely on a relatively small number of third parties for services and infrastructure related to our technology, and any loss or diminishment of any of those relationships could significantly harm our business, and we may be unable to find a suitable replacement for those functions in a reasonable amount of time, on favorable terms or at all.

Additionally, government and supranational regulation related to AI is evolving as new laws and regulations are implemented globally and could increase the burden and operational cost of compliance, including through requirements related to transparency, accountability, risk management, human oversight, and data governance. We expect to see increasing regulation related to AI governance, use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. The EU's Artificial Intelligence Act, or the AI Act, entered into force on August 1, 2024, with important sections scheduled to come into effect in August 2026. As currently enacted, the AI Act imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles when developing and using AI technology. The scope of requirements depends on legal and risk determinations that rely on legal provisions that have not yet been fully interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the current administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, there is continued uncertainty regarding the application of existing federal and state legal frameworks to uses and development of AI, and legal norms and market standards regarding AI continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use

AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific, potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools. Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy, data security and data integrity. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We are committed to implementing governance and control measures to mitigate these risks, but there can be no assurance that such measures will adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial conditions and results of operations.

If we do not succeed in our efforts to identify or discover additional potential product candidates, your investment may be lost.

The success of our business depends primarily upon our ability to identify, develop and commercialize drug products, an extremely risky business. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield potential product candidates for clinical development for several reasons, including:

- our research methodology or that of our partners may be unsuccessful in identifying potential product candidates;
- potential product candidates may have harmful side effects or may have other characteristics that make the products unmarketable or unlikely to receive marketing approval; and
- we or our partners may change their development profiles for potential product candidates or abandon a therapeutic area.

Such events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could cause us to cease operations. Research programs to identify new potential product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or potential product candidates that ultimately prove to be unsuccessful.

Because our future commercial success depends on gaining regulatory approval for our products, we cannot generate revenue without obtaining approvals.

Our long-term success and generation of revenue will depend upon the successful development of new products from our research and development activities, including those licensed or acquired from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, the FDA indicates that approximately 70% of drugs proceed past Phase 1 studies, 33% proceed past Phase 2, and just 25%-30% proceed past Phase 3 to Phase 4 which is the final phase in the FDA review and approval process for marketing therapeutic potential product candidates. The process for obtaining regulatory approval to market potential product candidates is expensive, usually takes many

years, and can vary substantially based on the type, complexity, and novelty of the potential product candidates involved. Our ability to generate revenue would be adversely affected if we are delayed or unable to successfully develop our products.

We may also pursue and deploy substantial resources and time towards seeking accelerated or limited approval processes that we may be deemed to not qualify for or may otherwise not be granted, in which case those efforts and resources will have been lost, and a delay or inability to obtain the approval for the applicable product candidate may result.

We cannot guarantee that any marketing application for our potential product candidates will be approved. If we do not obtain regulatory approval of our products or we are significantly delayed or limited in doing so, we cannot generate revenue, and we may need to significantly curtail operations.

If we are unable to successfully complete preclinical testing and clinical trials of our potential product candidates or experience significant delays in doing so, our business will be materially harmed.

We have invested and intend to continue to invest a significant portion of our efforts and financial resources in the identification and preclinical development of potential product candidates that target select diseases, including viral diseases and colon cancer. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our potential product candidates.

The commercial success of our potential product candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing and pricing approvals from regulatory authorities;
- obtaining and maintaining patent and trade secret protection for potential product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- commercializing our products, if and when approved, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete development of, or to successfully commercialize, our potential product candidates, which would materially harm our business. Pharmaceutical products that do overcome the low probability of success in drug development and achieve commercialization often do not recoup their cost of capital. If we are unable to design and develop each drug to meet a commercial need in the future, the approved drug may become a commercial failure and our investment in those development and commercialization efforts will have been commercially unsuccessful.

We may be unable to demonstrate safety and efficacy of our potential product candidates to the satisfaction of regulatory authorities, or we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of potential product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the potential product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not predict final results. For instance, we have disclosed certain results regarding measles and the Nipah virus based on molecular dynamics modeling. However, similar results from the molecular dynamics model may not be replicable in in vitro studies, in vivo studies and clinical trials. Moreover,

preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their potential product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events that may cause a delay or unsuccessful completion of clinical development include, among other things:

- delays in agreeing with the FDA or other regulatory authorities on final clinical trial design;
- imposition of a clinical hold following an inspection of a clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in agreeing on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the potential product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- negative or inconclusive results of clinical trials of potential product candidates;
- time and expenses required to add new clinical sites; or
- delays by contract manufacturers in producing and delivering sufficient supply of clinical trial materials.

If we or our partners must conduct additional clinical trials or other testing of any potential product candidates beyond those that are contemplated, or are unable to successfully complete clinical trials or other testing of any of our potential product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our partners may be subject to delays in or restriction from obtaining marketing approval for our potential product candidates, negative labeling and marketing requirements, additional post-marketing testing requirements, or actions by regulatory agencies to remove the product from a target market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our potential product candidates and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development, whether independently or with our partners, could cause additional costs to us or impair our ability to generate revenues from our potential product candidates, including product sales, milestone payments, profit sharing or royalties.

Even if the FDA grants breakthrough therapy designation for one or more of our potential product candidates, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our potential product candidates will receive marketing approval, and FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for breakthrough therapy.

We may seek a breakthrough therapy designation from the FDA for some of our potential product candidates that reach the regulatory review process. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed

early in clinical development. For drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our potential product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation.

The receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our potential product candidates qualify and are designated as breakthrough therapies, the FDA may later decide that the drugs or biological products no longer meet the conditions for designation and the designation may be rescinded.

Our potential product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events ("AEs") or serious adverse events ("SAEs"), that may be observed during clinical trials of our potential product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt such trials and could cause denial of regulatory approval. If AEs or SAEs are observed in any clinical trials of our potential product candidates, including those our partners may develop under alliance agreements, we or our partners' ability to obtain regulatory approval for potential product candidates may be negatively impacted.

Serious or unexpected side effects caused by an approved product could result in significant negative consequences, including the following:

- regulatory authorities may withdraw prior approval of the product or impose restrictions on our distribution in the form of a modified risk evaluation and mitigation strategy ("REMS") which may restrict the manner in which the product can be distributed or administered;
- we may be required to add labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we may decide or be forced to temporarily or permanently remove the affected product from one or more target markets or from the marketplace in general;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

These events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products and impair our ability to generate revenues from the commercialization of these products either by us or by our partners.

Following regulatory approval for a product candidate, we will still face extensive regulatory requirements, and the approved product may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States or elsewhere, the applicable regulators may still impose significant restrictions on the indicated uses or marketing of our potential product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The following discussion is based on United States law. Similar types of regulatory provision apply outside of the United States.

The holder of an approved new drug application ("NDA") must monitor and report AEs and SAEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws and are subject to FDA review.

Drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs, and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product such as AEs or SAEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our partners fail to comply with regulatory requirements following approval of our potential product candidates, a regulatory agency may:

- issue a warning letter asserting we are in violation of the law;
- impose a REMS, or other restrictions on the manufacturing, marketing or use of the product;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any clinical trials we may commence in the future;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Our defense of any government investigation of alleged violations of law, or any lawsuit alleging such violations, could require us to expend significant time and resources and could generate negative publicity. Further, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our potential product candidates or increase the cost of compliance. The occurrence of any event or penalty described above may prevent or inhibit our ability to commercialize our products and generate revenues.

We may not succeed in obtaining or maintaining necessary rights to drug compounds and processes for our development pipeline through acquisitions and in-licenses.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies are also pursuing strategies to license or acquire third-party intellectual property rights we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition, and prospects for growth could suffer.

Our product development programs are in the preclinical stage and we face significant competition from major companies who have developed or are developing vaccines or treatments for the diseases we are targeting, and if we fail to gain market share because our competitors develop and successfully commercialize vaccines or treatments, our business and future prospects could be materially and adversely affected.

We may be unable to develop or proceed with the onerous regulatory requirements for clinical programs necessary to produce an effective therapy in a timely manner or at all. Additionally, we are committing substantial financial and other resources to our drug development programs, which may occur at the expense of other potential drug candidate programs we could have otherwise and thereby negatively impact such other programs. Even if we do obtain FDA authorization for a therapeutic product, the FDA may subsequently rescind or limit such authorization as more information about the product, including its efficacy and side effects, become available. Further, a virus we target, such as COVID-19 which is highly mutative and for which a number of variants have already arisen, will render any potential product candidates we develop subject to the risk that a mutation will occur that produces a strain or strains of the virus to which such treatment has a diminished effect or is ineffective. If we do develop a treatment that is effective against a current version of a disease, a later variant may arise that reduces or eliminates the product's efficacy before we are able to commercialize it. Further, if this occurs, one or more competitors' products may be more effective against new variants than ours, resulting in a diminished market for our products. If we are unable to timely advance our programs, or if we fail to gain or maintain a market share as a result of our competitors developing and successfully commercializing effective vaccines and therapies more quickly than we do, our business and future prospects could be materially and adversely affected.

Further, because third parties may be developing competitive products without our knowledge, we may later learn that competitive products are superior to our potential product candidates which may force us to terminate our research efforts of one or more potential product candidates. If in the future, we learn of the existence of one or more competitive products, we may be required to cease our development efforts for a product candidate. Any of these events may occur after we have spent substantial sums in connection with the clinical research of one or more potential product candidates.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain approvals for marketing our potential product candidates, including approval by the FDA.

Our efforts to develop our potential product candidates are limited to a small number of potential product candidates aimed at treating a small number of viral diseases and colon cancer. To date, we have not advanced any potential product candidates to clinical trials, and we may be unable to progress our potential product candidates through the preclinical stage and into clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which we are pursuing development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay our effort to obtain marketing approval. We cannot guarantee that we will be able to proceed to clinical trials or that any future clinical trials will succeed. In fact, most compounds fail in clinical trials, even at companies far larger and more experienced than us. If any preclinical or clinical trials yield adverse results, this could delay the development of the product candidate, force us to cease pursuing the product candidate, or render it impossible or impracticable to proceed towards commercialization.

We have not obtained marketing approval or commercialized any of our potential product candidates. We may not successfully design or implement clinical trials required for marketing approval to market our potential product candidates. If we are unsuccessful in conducting and managing our preclinical development activities or clinical trials or obtaining marketing approvals, we might not be able to commercialize our potential product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Risks Related to Our Operations and Industry

If we cannot obtain or protect intellectual property rights related to our future products and potential product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our future products and potential product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent issuance of a patent based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed regarding our programs or potential product candidates fail to issue or if their breadth or strength of protection is threatened, this could dissuade companies from collaborating with us to develop potential product candidates and threaten our ability to commercialize products. Patents may not be issued and issued patents may be found invalid and unenforceable or challenged by third parties. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, we cannot be certain that we were the first to invent a patent application related to a product candidate. In certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding can be initiated to determine which applicant is entitled to the patent on that subject matter. Patents have a limited lifespan. In the United States, the natural expiration of a patent is 20 years after it is filed, although various extensions may be available. The life of a patent, and the protection it affords, is limited. When the patent life has expired for a product, we will become vulnerable to competition from generic medications attempting to replicate that product. Further, if we encounter delays in regulatory approvals, the time during which we will be able to market and commercialize a product candidate under patent protection could be reduced.

In addition to patent protection, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Each of our employees agrees to assign their inventions to us through an employee inventions agreement. In addition, as a general practice, our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology enter into confidentiality agreements. Nonetheless, our trade secrets and other confidential proprietary information may be disclosed, and competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

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 United States. We may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Further, governments may in the future alter intellectual property rights in a manner adverse to us or to our third-party collaborators, including actions taken at the international level.

If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

If third-party intellectual property infringement claims are asserted against us, it may prevent or delay our development and commercialization efforts and have a material adverse effect on our business and future prospects.

Our commercial success depends in part on us avoiding infringement on the patents and proprietary rights of third parties. There is substantial litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexaminations and other post-grant proceedings before the U.S. Patent and Trademark Office, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our partners are pursuing potential product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our potential product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology or rights without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our potential product candidates. Because patent applications can take many years to issue, there may be patent applications currently pending that may later result in patents that our potential product candidates may infringe upon. Third parties may obtain patents in the future and claim that use of our technologies infringes on these patents. If any third-party patents were to be held by a court of competent jurisdiction to cover the manufacturing process of any of our potential product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our potential product candidates. Defense of these claims, regardless of their merit, involves substantial litigation expense and diversion of our management's attention from our business. If a claim of infringement against us succeeds, we may have to pay substantial damages, possibly including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Because of the costs involved in defending patent litigation, we may in the future lack the capital to defend our intellectual property rights.

We may in the future be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe on our patents or the patents of our licensors. To counter such infringement or unauthorized use, we may be required to file infringement claims, or we may be required to defend the validity or enforceability of such patents, which can be expensive and time-consuming. In an infringement proceeding, a court may decide that either one or more of our patents or our licensors' patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue because our patents do not cover that technology. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions regarding our patents or patent applications or those of our partners or licensors. An unfavorable outcome could require us to cease using the related technology or to license rights to it from the prevailing party. Our business

could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense or pursuit of litigation or interference proceedings may fail and, even if successful, may cause us to incur substantial costs and distract the attention of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may need to obtain additional licenses to intellectual property rights from third parties.

We may need to obtain additional licenses from third parties to advance our research or allow commercialization of our potential product candidates. We may fail to obtain these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our potential product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales and other activities, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to develop and commercialize our potential product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities.

We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding potential product candidates that we may seek to acquire, in which case our business could be harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims asserting that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we succeed, litigation could cause substantial cost and be a distraction to our management and other employees.

Because we face significant competition from other biotechnology and pharmaceutical companies, our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources to be concentrated in our competitors. Additionally, smaller

or early-stage companies of which we may not be aware could also prove to be material competitors, particularly through collaborative arrangements with larger, more well-established companies or by competing with us for limited resources and strategic alliances with our current or prospective partners. Competition may increase further because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may develop, acquire or license drug products that are more effective or less costly than any product candidate we may develop.

The programs we are focusing on are in a preclinical stage and are targeted toward indications for which there are approved products on the market or potential product candidates in clinical development. We will face competition from other drugs that are or will be approved for the same therapeutic indications. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to discover and develop therapeutics superior to other products in the market, attract and retain qualified scientific, product development and commercial personnel, obtain and maintain patent and/or other proprietary protection for our technology platform and potential product candidates, obtain required regulatory approvals faster than competitors, and successfully collaborate with third parties with respect to these endeavors.

The availability of our competitors' products could limit the demand, and the price we can charge, for any products we may develop and commercialize. We will not achieve our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or reserve our products for use in limited circumstances. Additionally, the biopharmaceutical industry is characterized by rapid technological and scientific change, and we may not be able to adapt to these rapid changes to the extent necessary to keep up with competitors or at all. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our potential product candidates less competitive. Any new product that competes with an approved product must typically demonstrate advantages, such as in efficacy, convenience, tolerability or safety, to overcome price competition and to succeed. Our competitors may obtain patent protection, receive approval by the FDA and/or foreign regulatory authorities or discover, develop and commercialize potential product candidates before we do, which would have a material adverse impact on our business.

Our business could be negatively impacted by cybersecurity threats and other security threats and disruptions.

Because our business relies on proprietary data and related technology and computer systems, it faces certain security threats, including threats to our information technology infrastructure, attempts to gain access to our proprietary or confidential information, threats to physical security, and domestic terrorism events. Our information technology networks and related systems are critical to the operation of our business and our research and development efforts. We are also reliant on information technology systems operated by certain third parties, which generally face similar security threats and which third parties, and their activities are beyond our control. Cybersecurity threats in particular, are persistent, evolve quickly and include, but are not limited to, computer viruses, attempts to access information, denial of service and other electronic security breaches. We believe that we have implemented appropriate measures and controls and invested in skilled information technology resources to appropriately identify threats and mitigate potential risks, but there can be no assurance that such actions will be sufficient to prevent disruptions to critical systems, the unauthorized release of confidential information or corruption of data. A security breach or other significant disruption involving these types of information and information technology networks and related systems could:

- disrupt the proper functioning of these networks and systems and therefore our operations and/or those of third parties on which we rely;

- result in the unauthorized access to, and destruction, loss, theft, misappropriation or release of, our proprietary, confidential, sensitive or otherwise valuable information, or that of third parties with which we collaborate or otherwise depend, which others could use to compete against us or for disruptive, destructive or otherwise harmful purposes and outcomes;
- delay or compromise preclinical or clinical studies or the analysis and use of data collected in our efforts to develop potential product candidates;
- require significant attention and resources of management and key personnel to remedy any damages or other adverse consequences that result;
- subject us to claims for breach of contract, damages, credits, penalties or termination with respect to our relationships with third parties, or regulatory actions by governmental agencies; and
- damage our reputation with industry participants, existing or prospective strategic alliances, and the public generally.

Certain of our operations may have bearing on pandemic preparedness, national security and homeland defense, which increases the threat of cybersecurity attacks or incidents and the potential for losses, liability and other adverse consequences we could incur or experience as a result. Companies are increasingly suffering damage from attacks by hackers and there is a general risk that adversaries in geopolitical conflicts such as those taking place in Ukraine and in the Middle East adopt widespread Internet hacking as a weapon, which hacking may ultimately affect us. In the ordinary course of business, we store sensitive information, such as our intellectual property, including trade secrets and results of our research, and that of our suppliers and business partners, using online systems, and such information is sometimes transmitted via email correspondence. The secure maintenance and processing of this information is critical to our research and development activities and future operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breaches due to employee error, malfeasance or other disruptions. Any such unauthorized access, disclosure, misappropriation or other loss of information could result in disruption of our operations, including our existing and future research collaborations, and damage our reputation, which in turn could harm our business and future results of operations. The data and software on which our technology depends, as well as other information used in our operations, are trade secrets which are critical to our business, and any loss or unauthorized access or use thereof could materially harm our business.

Further, we are or may become subject to data privacy laws and regulations that could be implicated in our operations, including due to the issues described above. The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, federal, state and foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign and domestic citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business. Any of the foregoing events could have a material negative impact on our business, financial condition and prospects.

Failure of our information technology infrastructure to operate effectively could adversely affect our business.

We depend on information technology infrastructure to pursue our business objectives and development efforts with respect to our potential product candidates. If a problem occurs that impairs this infrastructure, including as a result of an outage or malfunctioning of the hardware and software comprising or contributing to the information technology, the resulting disruption could impede our ability to proceed with research objectives in a timely manner, or otherwise carry on business in the normal course. Any such events could cause us to lose opportunities or progress with respect to potential product candidates or strategic alliances, and could require us to incur significant expense to remediate.

The commercial success of our potential product candidates will depend upon the acceptance of these potential product candidates by the medical community, including physicians, patients and healthcare payors.

Assuming one or more potential product candidates achieve regulatory approval and we commences marketing such products, the market acceptance of any potential product candidates will depend on several factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any adverse effects or serious adverse effects;
- limitations on marketing or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- the timing of market introduction of our products relative to competitive products and the availability of alternative treatments;
- pricing and cost-effectiveness;
- the execution and effectiveness of our or any partners' sales and marketing strategies;
- our ability to obtain hospital formulary approval; and
- our ability to obtain and maintain sufficient third-party payor coverage or reimbursement.

In addition, healthcare reform measures such as the ACA and future government initiatives could have the effect of reducing prices for products we seek to commercialize in the future, thereby reducing our prospects for revenue and profitability with respect to any such products.

If we obtain regulatory approval for one product candidate, we expect sales to generate substantially all of our product revenues, and as such, the failure of such product to find market acceptance would adversely affect our results of operations.

Disruptions at the FDA, the SEC and other U.S. government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and our timelines.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, shifting policy priorities as a result of changes in the Presidential administration and political appointees tasked to oversee the agency, the availability of personnel and other resources, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine transactions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other U.S. government agencies or comparable foreign regulatory authorities on which our operations may rely is subject to the impacts of political events, including executive and congressional priorities, which are inherently fluid and unpredictable.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other agencies may slow the time necessary for product applications to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. Changes and cuts in FDA staffing have been reported by some in the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review investigational new drug applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Specifically, in 2025, the U.S.

government issued executive orders and implemented reductions in force that have adversely impacted FDA staffing and resources. If a prolonged government shutdown occurs or if staffing changes prevent the FDA, the SEC or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business and our timelines. Further, future government shutdown or other substantial disruption at other government agencies, such as the SEC, may also impact our business by delaying review of our public filings, which in turn could delay or frustrate our ability to access the public capital markets. Similar developments at regulators in other countries (including the EMA) could have similar impacts on our applications for marketing approval and on our business.

In addition, changes in the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our products, including applicable pricing and reimbursement frameworks under federal healthcare programs, could affect the commercial viability of our products, create revenue uncertainty, and impact our ability to achieve profitability. Regulatory challenges may introduce new challenges in obtaining FDA approval or navigating commercialization, and any delay in securing applicable regulatory approvals would adversely affect our business and prospects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our potential product candidates, we may be unable to generate any revenues from product sales.

We do not have a team with experience in the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or arrange with third parties to provide these services.

Our current and future partners may not dedicate sufficient resources to the commercialization of our potential product candidates or may otherwise fail in their commercialization efforts due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our potential product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future strategic partners do not successfully commercialize the potential product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our potential product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect to be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could cause increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is endemic;
- the impact of any war or hostilities such as those occurring in Ukraine and the Middle East;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in our compensation costs, our business may materially suffer.

We depend on principal members of our executive and research teams; the loss of whose services may adversely impact the achievement of our objectives. We are highly dependent on certain key personnel, particularly Frederick Pierce, our Chief Executive Officer, Peter Marschel, our Chief Business Officer, Barbara Hibner, our Chief Scientific Officer, and Michael Lipp, our Chief Technology Officer. If we lose the services of any of these individuals, we may be unable to locate replacements capable of performing these roles effectively, and any such individual will require high compensation in a competitive market for experienced and qualified personnel within our industry. We do not carry "key-man" life insurance on any of its employees or advisors. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees, our business may suffer.

Any relationships with customers and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our potential product candidates and commercialize those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. We may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009 , and our implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to violate any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, and curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our results of operations.

Because we will face potential product liability as we further develop potential product candidates and more so if we can commercialize any product candidate, if claims are brought against us, we may incur substantial liability and costs.

Using our potential product candidates in clinical trials and the sale of any products for which we obtain marketing approval will expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. These claims may allege that our products caused harm to them and/or that any adverse side effects or outcomes were not adequately disclosed or labelled. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Regardless of merit or eventual outcome, product liability claims may cause:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- regulatory scrutiny and product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our potential product candidates; and
- decreased demand for our potential product candidates, if approved for commercial sale.

Insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for potential product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Occasionally, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If we fail to comply with applicable laws and regulations, including environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the treatment of animals used in research. Our operations involve using hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. If contamination occurs or injury results from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

The Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to pathogens such as those we aim to treat. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

Although our workers' compensation insurance may cover us for costs and expenses, we may incur additional costs due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, and this insurance may not provide adequate coverage against other potential liabilities. We may incur substantial costs 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. Failure to comply with these laws and regulations also may cause substantial fines, penalties or other sanctions.

Our ability to use our net operating losses and tax credits to offset future taxable income and income tax liabilities may be limited.

At December 31, 2025, the Company had approximately $54.4 million of gross federal and $8.5 million of gross state net operating loss carry-forwards. Tax Cuts and Jobs Act ("TCJA") in 2017 amended the net operating losses carryforward rules. Net operating losses generated after December 31, 2017, may be carried forward indefinitely, subject to certain limitations on their use. Net operating losses generated prior to 2018 may be carried forward for twenty years. State net operating losses have varying carryforward and applicable expiration periods. $54.4 million of the federal net operating losses were incurred after December 31, 2017, and will be carried forward indefinitely; the balance of the federal net operating losses are subject to expiration no later than 2037. The utilization of such net operating loss carry-forwards and realization of tax benefits in future years depends predominantly upon having taxable income. The Company has approximately $3.5 million of federal research and development credits and $.4 million of state research and development credits which will begin to expire in 2040 if not utilized

In addition, under sections 382 and 383 of the Code, our federal net operating losses and tax credit carryforwards, such as research/development credits, may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders (or groups of stockholders) in excess of 50% over a rolling three-year period. Similar state provisions may also exist. These ownership changes may limit the amount of the net operating losses and tax credit carryforwards that can be utilized annually to offset future taxable income and income tax, respectively.

Entities are also required to evaluate, measure, recognize and disclose any uncertain federal or state income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2025, there were no uncertain tax positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2017 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant tax year to audit by The U.S. Internal Revenue Service ("IRS") and/or state taxing authorities. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the 12 months ended December 31, 2025 and 2024.

Business interruptions resulting from natural disasters and adverse weather events could cause delays in research and development of our potential product candidates.

We and third parties on which we rely upon are vulnerable to natural disasters such as earthquakes, tornados, severe storms, hurricanes, tsunamis, and fires, as well as other events that could disrupt our operations and cause delays in research and development of our potential product candidates. We do not carry insurance for natural disasters or similar events, and we may not carry sufficient business interruption insurance to compensate for losses that may occur. Any losses or damages we incur could have a material adverse effect on our operations.

Risks Related to Ownership of our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section, are:

- The price of our common stock may fluctuate substantially;
- volatility and limitations in trading volumes of our shares of common stock;
- speculative trading in and short sales of our stock, as well as trading phenomena such as the "short squeeze" and "short and distort" schemes;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- the timing and success of introductions of new applications and services by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our potential product candidates or any future clinical trials we may conduct;
- changes in the development status of our potential product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our potential product candidates;
- unanticipated safety concerns related to the use of our potential product candidates;

- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of our common stock or cause our stock price to decline.

We expect that significant additional capital will be needed in the future to continue our planned operations, including, without limitation, funding our trials and studies, marketing and commercializing our products and funding our operations. Accordingly, we have sold, and in the future may sell, common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent we raise additional capital by issuing additional shares of common stock or securities convertible or exchangeable for our common stock, our stockholders may experience substantial dilution, and new investors could gain rights superior to our existing stockholders.

Sales of a substantial number of our shares of common stock in the public markets, or the perception that such sales could occur, including from the exercise of warrants or sales of common stock issuable thereunder, could cause the market price of our shares of common stock to decline and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the number of these shares that might be sold nor the effect that future sales of our shares of common stock, including shares issuable upon the exercise of warrants, would have on the market price of our shares of common stock.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, we have no intention of paying any such dividends in the foreseeable future. Any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

If we were deemed to be an investment company under the Investment Company Act of 1940, as amended (the "1940 Act"), applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in the 1940 Act.

Notwithstanding Sections 3(a)(1)(A) and (C) of the 1940 Act, we are a research and development company and comply with the safe harbor requirements of Rule 3a-8 of the 1940 Act. We intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

We are a "smaller reporting company" and are able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company until we determine that either (1) our annual revenues are at least $100 million and our voting and non-voting common stock held by non-affiliates is at least $250 million measured on the last business day of our most recent second fiscal quarter, or (2) our voting and non-voting common stock held by non-affiliates is at least $700 million measured on the last business day of our most recent second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors. In addition, as a non-accelerated filer, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Our certificate of incorporation, our bylaws, and Delaware law may have anti-takeover effects that could discourage, delay, or prevent a change in control, which may cause our stock price to decline.

Our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued

in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. No preferred stock is currently outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management is required to devote substantial time to compliance matters.

As a publicly traded company we have incurred and will continue to incur significant legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly as we are no longer an “emerging growth company.” In addition, we expect these and similar rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain such insurance. Our continued compliance with applicable requirements and to keep pace with new regulations requires management and other personnel to devote a substantial amount of their time, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

General Risk Factors

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our

common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, which has occurred in the past, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our business, results of operations, financial condition and cash flows.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our business, financial condition, results of operations, and prospects. For example, the TCJA, the Coronavirus Aid, Relief and Economic Security Act, and the Inflation Reduction Act (the "IRA") made many significant changes to the U.S. tax laws. Beginning in 2022, the TCJA requires taxpayers to capitalize and amortize certain research and development expenditures over five years if incurred in the U.S. and 15 years if incurred in foreign jurisdictions, rather than deducting them currently. Although there have been legislative proposals to repeal or defer the research and development expenditure capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. As another example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a minimum tax on the book income of certain large corporations and a 1% excise tax on the value of certain corporate stock repurchases by publicly traded companies that would be imposed on the company repurchasing such stock. Regulatory or accounting guidance with respect to existing or future tax laws could materially affect our tax obligations and effective tax rate. It is uncertain if, and to what extent, various states will conform to current federal law or any newly enacted federal tax legislation.

Additional indirect taxes in various jurisdictions could materially adversely affect our business, financial condition, results of operations, and prospects.

We currently collect and remit applicable indirect taxes in jurisdictions where we, through our employees or economic activity, have a presence and where we have determined, based on applicable legal precedents, that our activities are taxable. We do not currently collect and remit indirect taxes, including state and local excise, utility user, and ad valorem taxes, fees, and surcharges in jurisdictions where we believe we do not have sufficient "nexus." Tax authorities may challenge our position that we do not have sufficient nexus in a taxing jurisdiction or that our activities are not taxable in such jurisdiction and may decide to audit our business and operations with respect to indirect taxes, which could result in significant tax liabilities (including related penalties and interest) for us or our customers, which could materially adversely affect our business, financial condition, results of operations, and prospects.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We maintain standard procedures to help assess, identify and manage material risk posed by cybersecurity threats and regularly evaluate how we can integrate these procedures into our overall risk management processes. For example, we require that all of our employees who have access to our internal network complete formal cybersecurity training upon hire and on a periodic basis, including training on phishing, malware, and other cybersecurity risks. We also continuously evaluate our information technology systems and our practices that relate to our information technology systems. To date, we have not engaged any formal assessment or cyber security auditors or other third parties in connection with these efforts but may elect to do so in the future.

To the extent we identify areas in our information systems that need improvement, we seek to timely implement and monitor such improvements. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third-party vendors that they have as well, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or those of our third-party vendors, that could materially adversely affect our business and financial condition. For additional information regarding whether risks from cybersecurity threats are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition, see Item 1A, “Risk Factors,” in this Annual Report on Form 10-K.

Governance

We currently engage a qualified IT consultant who reports to our Chief Executive Officer. This consultant has over 30 years of experience with cybersecurity, information technology development and deployment and information technology risk assessment and management, including information security management.

Our IT consultant regularly monitors our information technology systems and monitors the prevention, detection, mitigation and remediation of cybersecurity incidents in consultation with our Chief Executive Officer. Our Chief Executive Officer periodically reports information regarding our cybersecurity program to our Board, which has overall responsibility for risk oversight. In addition, our management is responsible for alerting our Board of any material cybersecurity incidents.

Over the last two years, we have not experienced any cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our business, results of operations, or financial condition.

Item 2. Properties

Our principal executive offices are in the Texas Medical Center in Houston, Texas, under a month-to-month lease. Currently, this facility consists of approximately 300 square feet and accommodates our general and administrative activities. We also maintain a facility at One Broadway, 14th Floor, Cambridge, MA 02142. Additionally, we lease laboratory space at 45-18 Ct Square W, Long Island City, NY 11101. Neither company owns any physical property, plants, or laboratories.

Item 3. Legal Proceedings

We are not currently a party to any legal proceedings the outcome of which we believe, if determined adversely to us, would individually or in the aggregate, have a material adverse effect on our business, financial condition, or results of operations. From time to time, we may become involved in legal proceedings arising in the ordinary course of business.

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 symbol "DCOY."

As of March 19, 2026, we had approximately 16 record holders of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these record holders.

Equity Compensation Plan Information

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference from Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

On December 12, 2024, we entered into a securities purchase agreement (the "ELOC Agreement") with C/M Capital Master Fund, LP (the "Purchaser"), we have issued and sold a total of 37,035 shares (the "Purchase Shares") of our common stock to the Purchaser pursuant to the ELOC Agreement at a weighted average exercise price of $128.76 for an aggregate purchase price of $4.8 million through March 27, 2026. These issuances and sales were made following written notice delivered by us to Investor, directing Investor to purchase the Purchase Shares. We also issued 370 shares of our common stock to the Purchaser as commitment shares pursuant to the terms of the ELOC Agreement.

During the three years ended December 31, 2025, we granted to our directors and officers options to purchase an aggregate of 115 shares of our common stock at exercise prices ranging from $734.40 to $822.38 per share, and 25 shares of restricted stock

Other than as described above or as previously disclosed on our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q filed with the SEC, we did not issue any unregistered equity securities during the twelve months ended December 31, 2025.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6.

RESERVED

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

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings Special Note Regarding Forward-Looking Statements" and "Risk Factors" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report. These risks could cause our actual results to differ materially from any future performance suggested below. The Merger (as defined below) of Salarius Pharmaceuticals, Inc. ("Salarius") and Decoy Therapeutics Inc. ("Legacy Decoy") closed on November 12, 2026. Accordingly, post-merger operating activities of Legacy Decoy have been included in the consolidated Financial Statements of the Combined Company (as defined below).

Introduction

Our Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows.

Overview

We are a pre-clinical stage biotechnology company focused on advancing our pipeline of peptide conjugate therapeutics engineered through our proprietary IMP^{3}ACT platform. Our IMP^{3}ACT platform represents a paradigm shift in peptide conjugate drug discovery and manufacturing, leveraging machine learning ("ML") and artificial intelligence ("AI") tools alongside high-speed synthesis techniques to rapidly engineer, optimize and manufacture peptide conjugates that target serious unmet medical needs. Peptide conjugates are emerging as a major therapeutic drug modality, with the potential to transform multiple therapeutic areas.Utilizing our novel IMP^{3}ACT platform that increases the drug development speed and reduce the complexity of variant synthesis, we aim to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology, with the goal of becoming a fully integrated biopharmaceutical company at the forefront of this field. Through this approach, we intend to revolutionize the design, development, and commercialization of peptide conjugate therapeutics. We have no products approved for commercial sales and have not generated any revenue from product sales.

Prior to January 8, 2026, we were known as Salarius Pharmaceuticals, Inc. In November 2025, ("Salarius or "Legacy Salarius"). completed a Merger (as defined below) with Legacy Decoy and conducted financings to raise capital for its business (together, along with future steps set forth elsewhere in this 10-K annual report, the "Decoy Transaction"). We refer herein to the post-transaction entity as the "Combined Company." In connection with the Decoy Transaction, on January 8, 2026, Salarius filed an amendment to its amended and restated certificate of incorporation to change its name to Decoy Therapeutics Inc. (the "Name Change"). Prior to the Name Change, the Combined Company's shares of common stock traded on the Nasdaq Capital Market ("Nasdaq") under the symbol "SLRX." Following the Name Change, the Combined Company's shares of common stock now trade on the Nasdaq under the symbol "DCOY."

The Merger (as defined below) combines our complementary approaches to create a comprehensive drug development platform. Our pipeline includes peptide conjugate drug candidates designed by our IMP^{3}ACT platform, as well as two small molecule drugs that address gene dysregulation: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat ("SP-2577"), a targeted protein inhibitor. SP-2577 has received FDA fast track designation as a potential treatment for Ewing sarcoma, a rare pediatric disease. We supported The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored clinical trial evaluating SP-2577 in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia through December, 2025. No further enrollment is planned. We intend to seek strategic alternatives for this program including potential out-licensing.

We plan to integrate our assets, particularly the proprietary compound SP-3164, to expand our opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras ("P-PROTACs"). We believe the synergies from the Merger are evident in our combined approach to drug development, integrating expertise in peptide conjugates with our small molecule assets. This combination enables us to address a wider range of diseases and potentially "undruggable" targets.

Recent Developments

Nasdaq Listing

On December 31, 2025, the Company received written notice from Nasdaq that it was not in compliance with Nasdaq Listing Rule 5550(a)(2) because the closing bid price of the Company's Common Stock for the last 30 consecutive business days was below the $1.00 per share minimum bid price requirement (the "Minimum Bid Price Requirement"). As the Company effected the 2025 Reverse Stock Split (as defined below) during the prior one-year period and remains subject to a mandatory panel monitor, the Company is not eligible for a 180-calendar day compliance period under Nasdaq listing rule 5810(c)(3)(A). The Company appealed the delisting determination by requesting a hearing before a Nasdaq Hearings Panel (the "Hearings Panel"). The Company presented its appeal to the Hearings Panel in early February 2026 and submitted a plan to regain compliance by March 20, 2026, including conducting a reverse stock split.

On March 13, 2026, the Company received a written notice from the Hearings Panel notifying the Company that it has been granted until March 20, 2026 to regain compliance with the Minimum Bid Price Requirement. . Pursuant to the Hearings Panel's decision, the continued listing of the Company's securities is subject to the condition that the Company must demonstrate compliance with the Minimum Bid Price Requirement on or before March 20, 2026. In connection with its compliance plan, the Company completed the 2026 Reverse Stock Split (as defined below) on March 6, 2026 and subsequently achieved a closing bid price of $7.47 on March 20, 2026, thereby demonstrating compliance with the Minimum Bid Price Requirement.

Closing of Decoy Merger

On January 10, 2025, the Company entered into an Agreement and Plan of Merger, as amended by the First Amendment on March 28, 2025, by the Second Amendment on June 10, 2025, by the Third Amendment on July 18, 2025, by the Fourth Amendment on July 29, 2025, and by the Fifth Amendment dated September 17, 2025 (as amended, collectively, the "Merger Agreement") with Decoy Therapeutics MergerSub I, Inc. ("MergerSub I"), Decoy Therapeutics MergerSub II, LLC ("MergerSub II"), and Legacy Decoy.

On November 12, 2025, pursuant to the Merger Agreement, MergerSub I merged with and into Legacy Decoy, and immediately thereafter Legacy Decoy merged with and into MergerSub II (the "Merger"), resulting in the Legacy Decoy business becoming a wholly owned subsidiary of the Company. The Merger is structured as a two-step transaction. In step one of the transaction, the Merger was consummated and all of Decoy's outstanding equity interests were exchanged based on an exchange ratio for consideration of shares of Salarius' Series A Preferred Stock. Additionally, certain holders of Decoy's non-convertible promissory notes (the "Decoy Promissory Notes") exchanged their notes for shares of Salarius' Series B Preferred Stock pursuant to note exchange agreements entered into in connection with the Merger, with the closing of such exchange to occur at the Merger Closing. The Series A Preferred Stock and the Series B Preferred Stock are newly designated series of preferred stock (collectively, the "Preferred Stock") that are intended to have economic rights equivalent to the Salarius common stock, but with only limited voting rights. The Series B Preferred Stock is identical in all material respects to the Series A Preferred Stock, except for certain redemption and conversion provisions that require (i) fifty percent (50%) of net proceeds from Salarius' "at-the-market" equity program and equity line of credit to be used for mandatory redemption of the Series B Preferred Stock until fully redeemed, (ii) optional redemption allowing Salarius to redeem all or any portion of the outstanding Series B Preferred Stock at any time following the Merger Closing, and (iii) optional conversion at the discretion of the holders upon

stockholder approval of the conversion of the Series B Preferred Stock and Salarius' achievement of the Nasdaq initial listing standards for a period of one year following such approvals, at which time remaining shares of Series B Preferred Stock shall automatically convert into Company common stock at the conversion ratio.

In connection with the Merger, the Company issued 877.709 shares of the Series A Preferred Stock and 796.306 shares of the Series B Preferred Stock to former Legacy Decoy stockholders and debtholders and reserved 45.098 shares of Series A Preferred Stock for assumed in-the-money options and warrants of Legacy Decoy. In connection with the adjustment to the conversion ratio in the certificate of designations for the Series A and Series B Preferred Stock triggered by the offering, the number of Company common shares underlying the issued and reserved shares of Series A and Series B Preferred Stock is 401,126. The shares of Series A Preferred Stock and Series B Preferred Stock are not convertible into Common Stock until such time as the Company's stockholders approve such conversion in accordance with Nasdaq Rule 5635 and the approval of the Company's initial listing application with Nasdaq. When converted, the conversion ratio applicable to the Common Stock issuable upon conversion will be adjusted pursuant to the March 6, 2026 1-for-12 reverse stock split.

In step two of the Merger, Salarius has agreed to call a special stockholder meeting to approve, among other things, the conversion of the Preferred Stock to be issued at the Merger Closing into shares of Salarius common stock (the "Conversion Proposal"). The Conversion Proposal was approved by sharedholders in February 2026. Nasdaq has informed Salarius that the Decoy transaction constitutes a business combination that will result in a "Change of Control" pursuant to Listing Rule 5110(a) in connection with step two of the transaction and that the post-transaction entity will be required to satisfy all of Nasdaq's initial listing criteria and to complete Nasdaq's initial listing process prior to Salarius' stockholder meeting to seek approval for the Conversion Proposal. Salarius therefore intends to commence the initial listing process following the consummation of this financing and the Merger Closing at such time that the post-transaction entity is expected to satisfy all of the applicable Nasdaq initial listing criteria. The Preferred Stock issued at the Merger Closing in connection with step one of the Decoy transaction will not be convertible into Salarius common stock until Nasdaq's approval of the initial listing application and stockholder approval of the Conversion Proposal.

Management and Director Changes

In connection with the Merger closing on November 12, 2025, Mr. Frederick E. Pierce was appointed Chief Executive Officer and Director; Dr. Barbara Hibner was appointed Chief Scientific Officer; and Mr. Peter Marschel was appointed Chief Business Officer. Mr. Mark Rosenblum will continue to serve as Executive Vice President and Chief Financial Officer (including as principal financial officer and principal accounting officer).

November 2025 Financing

On November 11, 2025, we entered into an underwriting agreement (the "Underwriting Agreement") with Ladenburg Thalmann & Co. Inc., as the sole underwriter (the "Representative"), relating to the issuance and sale in a public offering (the "November 2025 Offering") of: (i) 209,528 shares of the Company's Common Stock, (ii) pre-funded warrants to purchase up to 179,361 shares of Common Stock, (iii) Series A warrants to purchase up to 388,889 shares of Common Stock, (iv) Series B warrants to purchase up to 3,88.889 shares of Common Stock, and (v) up to 58,333 additional shares of Common Stock, Series A warrants to purchase up to an additional 58,333 shares of Common Stock and Series B warrants to purchase up to an additional 58,333 shares of Common Stock that may be purchased pursuant to a 45-day option to purchase additional securities granted to the Representative by the Company. The Representative exercised this option on November 11, 2025 for 55,477 shares of Common Stock, Series A warrants to purchase up to 58,333 shares of Common Stock and Series B warrants to purchase up to 58,333 shares of Common Stock. The combined public offering price of each share of Common Stock, together with the accompanying Series A warrants and Series B warrants, was $18, less underwriting discounts and commissions. The combined public offering price of each pre-funded warrant, together with the accompanying Series A warrants and Series B warrants, was $17.9988, less underwriting discounts and commissions. Subject to limited exceptions, a warrant holder may not exercise any portion of its warrants to the extent that the holder would beneficially own more

than 4.99% (or, at the election of the holder prior to the date of issuance, 9.99%) of the Company's outstanding Common Stock after exercise.

The November 2025 Offering, including the additional shares of Common Stock, Series A warrants and Series B warrants sold pursuant to the exercise of the Representative's option, closed on November 12, 2025.

The net proceeds from the Offering, including the additional shares of Common Stock, Series A warrants and Series B warrants sold pursuant to the exercise of the Representative's option, after deducting underwriting discounts and commissions and other estimated Offering expenses payable by the Company and excluding any net proceeds from the exercise of the Series A warrants, Series B warrants and pre-funded warrants, were approximately $6.3 million.

In connection with the November 2025 Offering, the Company and Equiniti Trust Company, LLC entered into a Warrant Agency Agreement pursuant to which Equiniti agreed to act as warrant agent with respect to the Series A warrants, the Series B warrants and the pre-funded warrants.

On November 12, 2025, pursuant to the Underwriting Agreement, the Company issued warrants to the Representative to purchase up to 22,218 shares of Common Stock at an exercise price of $27.9, subject to adjustments (the "Representative Warrants"). The Representative Warrants are exercisable at any time and from time to time, in whole or in part, until November 11, 2030, and have substantially similar terms to the Series A warrants.

All securities issued in the November 2025 Offering (including the shares of Common Stock issuable from time to time upon exercise of the warrants and the Representative Warrants) were offered pursuant to a registration statement on Form S-1, as amended, which became effective on November 10, 2025.

Reverse Stock Splits

On August 15, 2025, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-15 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "2025 Reverse Stock Split") which became effective as of August 18, 2025.

On March 5, 2026, the Company filed a Certificate of Amendment to the Company's amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-12 reverse stock split of the Company's issued and outstanding shares of Common Stock, par value $0.0001 per share (the "2026 Reverse Stock Split") which became effective as of March 6, 2026.

Going Concern

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception. We had an accumulated deficit of $94.4 million as of December 31, 2025. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

The lack of revenue from product sales to date and recurring losses from operations since our inception raise substantial doubt as to our ability to continue as a going concern. We will continue to require substantial additional capital to continue our operation and clinical development activities and may need such additional capital sooner than 12 months. As of December 31, 2025, we had cash and cash equivalents of $10.7 million, which includes approximately $3.0 million of cash that is restricted for use under the Gates Grant Agreement. Accordingly, we will need to raise substantial additional capital to continue to fund our operations beyond 2026. The amount and timing of our future funding requirements will depend on many factors, including the result of our strategic alternatives process, our ability to raise additional capital on commercially reasonable terms, the pace and results of clinical development

activities, and market conditions. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to continue our operations.

Results of Operations

The following table sets forth the consolidated results of our operations for the year ended December 31, 2025 compared to the year ended December 31, 2024.

	Year Ended December 31, 2025	2024	Change $
Acquired in-process research and development expenses	8,517,966	-	8,517,966
Research and development expenses	368,170	770,027	(401,857)
General and administrative expenses	3,727,816	4,964,289	(1,236,473)
Interest income, net	95,472	158,539	(63,067)
Net loss	$ (12,518,480)	$ (5,575,777)	$ (6,942,703)

Research and Development Expenses

Research and development expenses were $8.9 million during the year ended December 31, 2025 compared to $0.8 million during the year ended December 31, 2024. This increase of $8.1 million principally resulted from IPR&D assets acquired in connection with the Merger.

	SP - 3164		SP- 2577		IPR&D		IMP^{3}ACT	
	2025	2024	2025	2024	2025	2024	2025	2024
Research and development costs by candidates and by categories:								
Outsourced research and development costs	$ 8,835	$ 69,753	$ (109,506)	$ 345,228	$ —	$ —	$ —	$ —
Employee-related costs						—		—
Manufacturing and laboratory costs	47,462	275,827	114,047	79,219	—	—	—	—
In process research and development costs					8,517,966	—	307,332	—
Total research and development costs	**$ 56,297**	**$ 345,580**	**$ 4,541**	**$ 424,447**	**$ 8,517,966**	**$ —**	**$ 307,332**	**$ —**

General and Administrative Expense

General and administrative expenses were $3.7 million for the year ended December 31, 2025 compared to $5.0 million for the year ended December 31, 2024, the decrease is mainly driven by lower personnel costs, public company expenses and D&O insurance cost. *The Merger was closed on November 12, 2026. Accordingly, post-merger operating activities of Legacy Decoy have been included in the consolidated Financial Statements of the Combined Company.*

Liquidity and Capital Resources

Current and Future Financing Needs

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for the foreseeable future. We have not generated any cash inflows from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and

until we obtain regulatory approval for and commercializes any of our potential product candidates, all of which are in early stages of development.

During the twelve months ended December 31, 2025, we received $0.8 million and $12.3 million of cash from investing in the asset acquisition and financing activities, respectively. As of December 31, 2025, we had $5.8 million of working capital and our cash and cash equivalents totaled $10.7 million, which were held in bank and money market accounts. Approximately $3.0 million of our December 31, 2025 cash position is restricted for use under our Gates Grant Agreement and can only be used for specific development purposes, not for general or administrative purposes. Our cash and cash equivalents balance increased during the year ended December 31, 2025, primarily due to financing and investing activities offset by capital used in operations. Under current operating conditions, we believe that our cash and cash equivalents on hand as of December 31, 2025 is sufficient to fund our anticipated operations into late 2026. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders.

Cash Flow

	Year Ended December 31, 2025	2024
Net cash (used in) provided by:		
Operating activities	$ (4,827,188)	$ (4,525,337)
Investing activities	764,735	-
Financing activities	12,337,862	1,059,955
Net decrease in cash, cash equivalents, and restricted cash	$ 8,275,409	$ (3,465,382)

	Year Ended December 31, 2025	2024
Proceeds from issuance of equity securities	12,559,728	1,526,460
Payments on note payable	(221,866)	(466,505)
Net cash provided by financing activities	**$ 12,337,862**	**$ 1,059,955**

Operating Activities

Net cash used in operating activities was $4.8 million for the year ended December 31, 2025, compared to $4.5 million for the year ended December 31, 2024. The increase is primarily due to general administrative activities. From an operational perspective, the Company incurred lower Legacy Salarius spending year to year. Combined Company expenses are included for the period from November 12, 2025 through December 31, 2025.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's 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 GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the consolidated balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our consolidated financial statements prospectively from the date of the change in estimate.

Our significant accounting policies are described in Note 2 to our audited consolidated financial statements for the year ended December 31, 2025 in this Annual Report on Form 10-K. The Company evaluates acquisitions to determine whether the transaction should be accounted for as a business combination or an asset acquisition. Transactions that do not meet the definition of a business are accounted for as asset acquisitions. Asset acquisitions typically consist of acquired in-process research and development ("IPR&D") programs, technology rights, licenses, or other intangible assets that do not have alternative future use at the acquisition date. The total consideration transferred in an asset acquisition is allocated to the individual assets acquired on a relative fair value basis. Transaction costs incurred in connection with asset acquisitions are capitalized as part of the cost of the acquired assets. Significant judgment is required in determining the fair value of the consideration transferred, which may include cash, equity instruments, or contingent consideration such as development, regulatory, or commercial milestone payments. The fair value of equity instruments issued as consideration is measured at the acquisition date based on the Company's market price or, in the absence of a quoted market price, using valuation techniques that require assumptions about expected volatility, term, and marketability. Acquired IPR&D assets that do not have alternative future use are expensed as research and development costs at the acquisition date. If an acquired asset has alternative future use, the asset is capitalized and amortized over its estimated useful life once placed in service. Because asset acquisitions are often unique and involve early-stage technologies, changes in assumptions related to the determination of alternative future use, estimated useful lives, or the timing and probability of milestone payments could have a material impact on the Company's results of operations and financial position. We have identified this policy as critical because it is important to the presentation of our financial condition and results of operations and requires us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. For more information regarding these policies, you should refer to Note 2 of our audited consolidated financial statements included in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and does not have any holdings in variable interest entities.

Application of New Accounting Standards

See Note 2 – Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial positions and cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

DECOY THERAPEUTICS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Decoy Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Decoy Therapeutics Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a 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 financial statements, the Company has a lack of revenue from product sales and has had recurring losses from operations since its inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Valuation of preferred stock

Description of the Matter	As discussed in Note 3 to the consolidated financial statements, the Company issued preferred stock as part of the consideration transferred in its asset acquisition with a fair value of $4,302,000 as of November 12, 2025. The fair value of the preferred stock was estimated using a Monte Carlo simulation, which considers various potential scenarios. We identified the valuation of the preferred stock as a critical audit matter because it required the use of a complex valuation model that included a subjective equity volatility assumption. Changes in this assumption could have had a significant effect on the fair value of the preferred stock.
How We Addressed the Matter in Our Audit	Our audit procedures included, among others, testing inputs by comparing them to external market data and contractual terms and involving our valuation specialists to assist in assessing the reasonableness of the valuation model, validating significant assumptions, and performing a corroborative calculation.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.
Houston, Texas
March 31, 2026

DECOY THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 10,709,937	$ 2,434,528
Prepaid expenses and other current assets	275,223	553,034
Total current assets	10,985,160	2,987,562
Property and equipment, net	40,559	—
Other assets	30,988	35,412
Total assets	$ 11,056,707	$ 3,022,974
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 940,586	$ 936,994
Accrued expenses and other current liabilities	859,442	352,419
Deferred revenue	3,225,581	—
Note payable	—	221,866
Due to related party	139,823	—
Other current liability	2,306	—
Total current liabilities	5,167,738	1,511,279
Total liabilities	$ 5,167,738	$ 1,511,279
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; 1,674 and 0 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized; 531,968 and 8,006 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	53	1
Additional paid-in capital	100,331,014	83,435,312
Accumulated deficit	(94,442,098)	(81,923,618)
Total stockholders' equity	5,888,969	1,511,695
Total liabilities and stockholders' equity	$ 11,056,707	$ 3,022,974

Historical common stock and additional paid-in capital amounts have been recast to reflect the 1-for-8, 1-for-15 and 1-for-12 reverse stock splits effected on June 14, 2024, August 15, 2025 and March 6, 2026, respectively.

See accompanying notes to consolidated financial statements.

DECOY THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2025	Year Ended December 31, 2024
Operating expenses:		
Acquired in-process research and development	8,517,966	—
Research and development	368,170	770,027
General and administrative	3,727,816	4,964,289
Total operating expenses	12,613,952	5,734,316
Loss from operations	(12,613,952)	(5,734,316)
Interest income and other, net	95,472	158,539
Net loss	$ (12,518,480)	$ (5,575,777)
Loss attributable to common stockholders	$ (12,518,480)	$ (5,575,777)
Net loss per share attributable to common stockholders — basic and diluted	$ (129.10)	$ (69.54)
Total net loss per share	$ (129.10)	$ (69.54)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	96,967	80,184

Historical common stock and additional paid-in capital amounts have been recast to reflect the 1-for-8, 1-for-15 and 1-for-12 reverse stock splits effected on June 14, 2024, August 15, 2025 and March 6, 2026, respectively.

See accompanying notes to consolidated financial statements.

DECOY THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2025	Year Ended December 31, 2024
Operating activities		
Net loss	$ (12,518,480)	$ (5,575,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and impairment	7,151	4,424
Equity-based compensation	219,058	273,730
Change in fair value of warrant liability	(6,540)	—
In-process research and development expense	8,517,966	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	419,628	492,471
Accounts payable	(1,167,068)	334,141
Accrued expenses	(298,903)	(54,326)
Net cash used in operating activities	(4,827,188)	(4,525,337)
Investing activities		
Issuance of promissory loan in connection with asset acquisition	(577,000)	—
Cash received from asset acquisition, net of cash paid	1,341,735	—
Net cash provided by investing activities	764,735	—
Financing activities		
Proceeds from issuance of equity securities, net	12,559,728	1,526,460
Payments on note payable	(221,866)	(466,505)
Net cash provided by financing activities	12,337,862	1,059,955
Net increase (decrease) in cash, cash equivalents , and restricted cash	8,275,409	(3,465,382)
Cash, cash equivalents, and restricted cash at beginning of period	2,434,528	5,899,910
Cash, cash equivalents, and restricted cash at end of period	$ 10,709,937	$ 2,434,528
Supplemental cash flow information		
Cash paid for interest	$ 5,800	$ 10,643
Preferred stock issued for in-process research and development technology	4,302,000	—
Accrued issuance costs for public offering	185,032	—
Settlement of promissory loans in connection with asset acquisition	577,000	—
Prepaid expense financed by note payable	—	398,728

See accompanying notes to consolidated financial statements.

DECOY THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2023	**2,735**	**—**	**—**	**—**	**81,635,123**	**(76,347,841)**	**5,287,282**
Issuance of equity securities, net	5,271	1	—	—	1,526,459	—	1,526,460
Equity-based compensation expense					273,730	—	273,730
Net loss	—	—	—	—	—	(5,575,777)	(5,575,777)
Balance at December 31, 2024	**8,006**	**1**	**—**	**—**	**83,435,312**	**(81,923,618)**	**1,511,695**
Issuance of equity securities, net	523,962	52		—	12,374,644	—	12,374,696
Equity-based compensation expense	—	—	—	—	219,058	—	219,058
Preferred stock issued for asset acquisition			1,674	—	4,302,000		4,302,000
Net loss	—	—	—	—	—	(12,518,480)	(12,518,480)
Balance at December 31, 2025	**531,968**	**53**	**1,674**	**—**	**100,331,014**	**(94,442,098)**	**5,888,969**

Historical common stock and additional paid-in capital amounts have been recast to reflect the 1-for-8, 1-for-15 and 1-for-12 reverse stock splits effected on June 14, 2024, August 15, 2025 and March 6, 2026, respectively.

See accompanying notes to consolidated financial statements.

DECOY THERAPEUTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND OPERATIONS

Nature of Business

Decoy Therapeutics Inc.. (“Decoy” or the “Company”), together with its subsidiaries, Salarius Pharmaceuticals, LLC, Flex Innovation Group LLC, and TK Pharma, Inc., is a pre-clinical stage biotechnology company focused on advancing our pipeline of peptide conjugate therapeutics engineered through a proprietary IMP3ACT™ platform. Utilizing a novel IMP3ACT™ platform that increase the drug development speed and reduce the complexity of variant synthesis, the Company aims to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology. The Company currently has no products approved for commercial sales and has not generated any revenue from product sales.

Prior to January 8, 2026, the Company was known as Salarius Pharmaceuticals, Inc. (“Salarius”). In November 2025, Salarius completed a Merger (as defined below) with Decoy Therapeutics Inc. (“Legacy Decoy”) and conducted financings to raise capital for its business (together, along with future steps set forth elsewhere in this Annual Report on Form 10-K, the “Decoy Transaction”). We refer herein to the post-transaction entity as the “Combined Company.” In connection with the Decoy Transaction, on January 8, 2026, Salarius filed an amendment to its amended and restated certificate of incorporation to change its name to Decoy Therapeutics Inc. (the “Name Change”). Prior to the Name Change, the Combined Company’s shares of common stock traded on the Nasdaq Capital Market (“Nasdaq”) under the symbol “SLRX.” Following the Name Change, the Combined Company’s shares of common stock now trade on the Nasdaq under the symbol “DCOY.”

The Merger combines our complementary approaches to create a comprehensive drug development platform. The Company's pipeline includes peptide conjugate drug candidates designed by our IMP^{3}ACT platform, as well as two small molecule drugs that address gene dysregulation: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat (“SP-2577”), a targeted protein inhibitor. SP-2577 has received FDA fast track designation as a potential treatment for Ewing sarcoma, a rare pediatric disease. We support The University of Texas MD Anderson Cancer Center (“MDACC”) in MDACC’s sponsored clinical trial evaluating SP-2577 in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia, which is currently enrolling patients. The Company plans to integrate our assets, particularly the proprietary compound SP-3164, to expand the Company's opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras (“P-PROTACs”). The Company believes the synergies from the Merger are evident in our combined approach to drug development, integrating expertise in peptide conjugates with our small molecule assets. This combination enables the Company to address a wider range of diseases and potentially “undruggable” targets.

Going Concern

Decoy has no products approved for commercial sale, has not generated any revenue from product sales to date and has had recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Based on Decoys’ expected cash requirements, Decoy believes that there is substantial doubt that its existing cash and cash equivalents, will be sufficient to fund its operations through one year from the financial statements' issuance date. The Company may attempt to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also

consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

If the Company is unable to obtain additional capital in the very near term, it will be forced to cease operations, liquidate its assets and pursue the winding down and dissolution of the Company.

Reverse Stock Splits

On March 5, 2026, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-12 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "2026 Reverse Stock Split") which became effective as of March 6, 2026.

On August 15, 2025, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-15 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "2025 Reverse Stock Split") which became effective as of August 18, 2025.

On June 14, 2024, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-8 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share, which became effective as of June 14, 2024 (the "2024 Reverse Stock Split", and together with the 2025 Reverse Stock Split and the 2026 Reverse Stock Split, the "Reverse Stock Splits").

All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Splits.

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The Company considered its going concern disclosure requirements in accordance with ASC 205-40-50.The Company has performed an analysis and concluded substantial doubt exists with respect to the Company being able to continue as a going concern through one year from the date of issuance of the consolidated financial statements for the year ended December 31, 2025.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America as defined by the FASB ASC requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

Decoy considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. Approximately $3.0 million of our December 31, 2025 cash position is restricted for use under our Gates Grant Agreement. There was no restricted cash at December 31, 2024.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment charges related to long-lived assets during the twelve months ended December 31, 2025 and 2024.

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and restricted cash. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation (“FDIC”). Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Warrants

The Company determines whether warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs with changes in fair value recorded in the Consolidated Statement of Operations within change in fair value of warrant liability. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant. For warrants classified as equity contracts, the Company allocates the transaction proceeds to the warrants and any other free-standing instruments issued in the transaction based on an allowable allocation method.

Clinical Trial Accruals

The Company’s preclinical and clinical trials are performed by third party contract research organizations (CROs) and/or clinical investigators, and clinical supplies are manufactured by contract manufacturing organizations (CMOs). Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon its assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. The Company’s estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies, and may not match the actual services performed by the organizations. This could result in adjustments to the Company’s research and development expenses in future periods. To date the Company has had no significant adjustments.

Research and Development Costs

Research and development costs consist of expenses incurred in performing research and development activities, including pre-clinical studies and clinical trials. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities, license fees and other external costs. Research and development costs are expensed when incurred.

Equity-Based Compensation

Salarius measures equity-based compensation based on the grant date fair value of the awards and recognizes the associated expense in the financial statements over the requisite service period of the award, which is generally the vesting period.

The Company uses the Black-Scholes option valuation model to estimate the fair value of the stock-based compensation and incentive units. Assumptions utilized in these models include expected volatility calculated based on implied volatility from traded stocks of peer companies, dividend yield and risk-free interest rate. Additionally, forfeitures are accounted for in compensation cost as they occur.

Segment Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or CODM, in making decisions on how to allocate resources and assess performance. The CODM is the Company’s Chief Executive Officer. The Company views its operations as and manages its business in one operating segment, focused on the discovery and development therapeutics for patients with high, unmet medical needs. The Company operates in one geographic segment. Segment information is further described in Note 12, “Segment Reporting”.

Loss Per Share

Basic net loss per share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is anti-dilutive.

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, (iii) unvested restricted stock and (iv) rights entitling holders to receive warrants to purchase the Company's common shares, which have been excluded from the computation of diluted loss per share, was 1,347,865 and 3,291 shares as of December 31, 2025 and 2024, respectively.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore, a valuation allowance has been established for the full amount of the deferred tax assets.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2025 and 2024, the Company did not have any significant uncertain tax positions and no interest or penalties have been charged. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company is subject to routine audits by taxing jurisdictions.

Asset Acquisitions

In accordance with the guidance in Topic 805, Business Combinations, in the Financial Accounting Standards Board's (the FASB) Accounting Standards Codification (ASC), the Company evaluates acquisitions of assets and related liabilities and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business. The Company accounts for an asset acquisition by recognizing net assets based on the cost to the acquiring entity on a relative fair value basis. Goodwill is not recognized in an asset acquisition; any excess consideration transferred over the fair value of the net assets acquired is allocated to the non-monetary identifiable assets and liabilities assumed based on relative fair values. In-process research and development acquired in an asset acquisition is expensed provided there is no alternative future use. The Company accounts for future payments such as those upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying milestones are achieved. Milestone payments made to third parties subsequent to regulatory approval may be capitalized as intangible assets, if deemed to have alternative future use, and amortized over the estimated remaining useful life of the related product.

Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU No. 2024-03"), which requires disaggregated disclosure of certain costs and expenses, including purchases of inventory, employee compensation, depreciation, amortization and depletion, within relevant income statement captions. ASU No. 2024-03 is effective for annual periods beginning after December 15, 2026 and for interim periods beginning after December 15, 2027 on a retrospective or prospective basis, with early adoption permitted. The Company is evaluating the effect that ASU No. 2024-03 will have on its financial statement disclosures.

In July 2025, the FASB issued ASU No. 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets, which allows an entity to elect a practical expedient for measuring expected credit losses on current accounts receivable and current contract assets arising from transactions accounted for as revenues from contracts customers. The ASU is effective for fiscal years beginning after December 15, 2025, and interim periods within those fiscal years on a prospective basis. Adoption is expected to have an immaterial effect on our consolidated financial statements.

In December 2025, FASB issued ASU 2025-10, Financial Instruments - Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which establishes authoritative guidance on the recognition, measurement, presentation, and disclosure of government grants received by business entities. The update provides a framework for determining when a grant should be recognized in income and includes enhanced disclosure requirements. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, and interim periods within those fiscal years. Adoption is expected to have an immaterial effect on our consolidated financial statements.

Recently Adopted Accounting Standards

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which is intended to improve the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid by jurisdiction. The ASU is effective for public business entities for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has adopted ASU No. 2023-09 prospectively in its fiscal year 2025. Adoption has an immaterial effect on our consolidated financial statements.

NOTE 3. ASSET ACQUISITION

On January 10, 2025, the Company entered into an Agreement and Plan of Merger, as amended by the First Amendment on March 28, 2025, by the Second Amendment on June 10, 2025, by the Third Amendment on July 18, 2025, by the Fourth Amendment on July 29, 2025, and by the Fifth Amendment dated September 17, 2025 (as amended, collectively, the “Merger Agreement”) with Decoy Therapeutics MergerSub I, Inc. (“MergerSub I”), Decoy Therapeutics MergerSub II, LLC (“MergerSub II”), and Legacy Decoy. On November 12, 2025 (the "Merger Date"), pursuant to the Merger Agreement, MergerSub I merged with and into Legacy Decoy, and immediately thereafter Legacy Decoy merged with and into MergerSub II (the “Merger”), resulting in the Decoy business becoming a wholly owned subsidiary of the Company.

In connection with the Merger, the Company issued 877.709 shares of Series A Non-Voting Convertible Preferred Stock (the "Series A Stock") and 796.306 shares of Series B Non-Voting Convertible Preferred Stock (the "Series B Stock") to former Legacy Decoy stockholders and debtholders. In connection with the adjustment to the conversion ratio in the certificate of designations for the Series A and Series B Preferred stock triggered by the Offering, the number of Company common shares underlying the issued and reserved shares of Series A and Series B Preferred Stock is 401,126. The shares of Series A Preferred Stock and Series B Preferred Stock are not convertible into common stock until such time as the Company’s stockholders approve such conversion in accordance with Nasdaq Rule 5635 and the approval of the Company’s initial listing application with Nasdaq.

In accordance with the ASC Topic 805, Business Combinations, the Company first evaluated the initial screen test to determine if substantially all of the fair value of the gross assets acquired from Decoy was concentrated in a single asset or a group of similar assets. The Company concluded that substantially all of the fair value of the gross assets being acquired from Decoy was concentrated in the in-process research and development (IPR&D) related to a single asset. Accordingly, the Company accounted for the acquisition as an asset acquisition. In accordance with the asset acquisition method of accounting, the cost of the asset acquisition, which reflects the consideration transferred, (i) was allocated to the assets acquired and liabilities assumed on a relative fair value basis, (ii) no goodwill was recorded and (iii) all direct transaction costs were included in the total consideration transferred.

Consideration Transferred and Purchase Price Allocation

As illustrated further below, the $8.5 million of the consideration transferred that was allocated to the IPR&D represents the residual portion of the total cost of the Merger, including consideration transferred and liabilities assumed, after allocating amounts to all other acquired assets based on their estimated relative fair values. In accordance with ASC 730, Research and Development, the entire amount allocated to IPR&D was immediately expensed on the Merger Date, as the IPR&D was determined to have no future alternative use at the closing of the Merger. The following is the total consideration transferred and allocation of the purchase consideration for the acquisition based on the relative fair value of the net assets acquired by the Company.

Equity consideration	$	4,302,000
Settlement of pre-existing loan		577,000
Settlement of Legacy Decoy Debt		649,555
Transaction costs		1,059,249
Total Consideration	**$**	**6,587,804**
Assets acquired		
Cash, cash equivalents and restricted cash		2,970,690
Prepaid expenses and other current assets		141,818
Fixed assets, net		43,286
In-process research and development assets		8,517,966
Total assets acquired	$	11,673,760
Liabilities assumed		
Accounts payable		(1,055,780)
Accrued expenses		(655,926)
Deferred grant revenue		(3,225,581)
Notes payable, related party		(139,823)
Other liability		(8,846)
Total liabilities assumed	$	(5,085,956)
Net assets acquired	**$**	**6,587,804**

- Equity consideration: Consists of the issuance of 877.709 shares of the Company's Series A Stock and 796.306 shares of the Company's Series B Stock with an estimated aggregated fair value of $4,302,000, determined using a Monte Carlo simulation model.
- Settlement of pre-existing loan: In 2025, Legacy Salarius issued three promissory notes to Legacy Decoy in the aggregated principal amount of $577,000 prior to the consummation of the Merger. Upon closing of the Merger, the loan was eliminated as the preexisting relationship was effectively settled and included in consideration transferred. Further, as the carrying value of the Loan was determined to approximate fair value at the time of the Merger, no gain or loss was recorded upon the effective settlement.
- Transaction costs: Represents the direct transaction costs, primarily legal and advisory services incurred by the Company in connection with the Merger.
- Deferred grant revenue: The Company received a foundation grant from the Gates Foundation for the development of a nasally inhaled, low cost, peptide conjugate pan-Coronavirus antiviral inhibitor. Please refer to Note 6 for further discussion.

NOTE 4. DEFERRED REVENUE AND GRANT REVENUE

Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. Deferred revenue balances were $3.2 million and $0 as of December 31, 2025 and December 31, 2024, respectively.

Legacy Decoy has received grants from two funding sources, including a private not-for-profit organization and a federal agency. Funds received in advance of services being performed are recorded as deferred revenue. Income under the not-for-profit and federal agency grants is recognized as labor and material costs are incurred. Labor costs are recognized based on actual salary costs incurred related to the projects, and material costs are recognized based on actual expenditures.

NOTE 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2025 and 2024 consisted of the following:

	December 31, 2025	December 31, 2024
Prepaid insurance	$ —	$ 287,785
Deferred offering cost	—	221,580
Other prepaid and current assets	275,223	43,669
Total prepaid expenses and other current assets	$ 275,223	$ 553,034

Prepaid insurance is mainly comprised of prepaid directors' and officers' insurance. In July 2024, the Company financed its directors and officers' insurance premium with a short term note the principal amount of which is approximately $0.4 million bearing interest at a rate of 9.74%. The note payable balance, which was included within Current Liabilities on the Consolidated Balance Sheet was $0 million and $0.2 million as of December 31, 2025 and 2024

The Company recorded $221,580 of certain legal, professional accounting and other third-party fees that are directly associated with equity financings as deferred offering costs in 2024 until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of the offering.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Key Relationship and Licenses

Legacy Decoy has received non-dilutive investments from the European Union’s IMI-CARE Consortium, The Gates Foundation, The U.S. Government’s Biological Research and Development Authority (“BARDA”) and Johnson & Johnson through the U.S. Government’s Blue Knight Program.

Gates Foundation

The Company received a foundation grant from the Gates Foundation for the development of a nasally inhaled, low cost, peptide conjugate pan-Coronavirus antiviral inhibitor. The initial award in September 6, 2021 provided up to a total of approximately $904,000 and expired on February 28, 2023. Legacy Decoy initially recorded the proceeds in deferred revenue. As work commenced under the grant, the Company recognizes income from deferred revenue.

In 2023 the Company entered into a supplemental grant with the Gates Foundation for an additional $4,084,500 for continued work on the nasally inhaled, low cost, peptide conjugate pan-Coronavirus antiviral inhibitor reference above. The Company received payment of $3,500,000 on September 28, 2023. The remaining $584,500 will be received after the completion of certain milestones.

The Company had approximately $2.9 million in both deferred revenue balance and restricted cash related to this grant at December 31, 2025.

Johnson and Johnson Quickfire Grants

The Company received a grant from the Johnson and Johnson through the U.S. government’s Blue Knight Program (Quickfire Grant) for experiments relating to the pharmacokinetics and tolerability of the aforementioned pan-Coronavirus inhibitor in the Human Airway Epithelium (HAE) model. The initial award to the Company on January 31,

2023 provided for $100,000. The Company initially recorded the proceeds in deferred income. As work commenced under the grant, the Company recognizes income.

On September 22, 2023 the Company received the first $500,000 of an additional Quickfire grant for $1,000,000 for work to investigate the potential for broader therapeutic use of the aforementioned pan-Coronavirus inhibitor. The Company initially recorded the proceeds in deferred revenue. As work commenced under the grant, the Company recognizes income from deferred income.

On December 1, 2023 the Company received a second $500,000 of the Quickfire grant mentioned above. The Company initially recorded the proceeds in deferred income. As work commenced under the grant, the Company recognizes income from deferred income.

On March 25, 2024 the Company received a grant of $250,000 from Johnson and Johnson through the U.S. government's Blue Knight Program (Quickfire Grant) for experiments relating to the pharmacokinetics and tolerability of the aforementioned pan-Coronavirus inhibitor in the Human Airway Epithelium (HAE) model. At year end December 31, 2025 the Company has the proceeds recorded in deferred revenue. As work is commenced under the grant, the Company will recognize income from deferred income.

The Company recognized income of approximately $0 for the years ended December 31, 2025 and December 31, 2024.

Cancer Prevention and Research Institute of Texas

In June 2016, the Company entered into a Cancer Research Grant Contract with CPRIT. Pursuant to the contract, CPRIT awarded the Company a grant up to $18.7 million, further modified to $16.1 million to fund development of LSD 1 inhibitor. The grant expired during 2023.

The Company agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes. The Company agreed to retain its Texas headquarters address for three year post grant expiration.

The Company is obligated to make revenue-sharing payments to CPRIT with respect to net sales of any product covered by the contract, up to a maximum repayment of certain percentage of the aggregate amount paid to the Company by CPRIT under the CPRIT contract. The payments are determined as a percentage of net sales, which may be reduced if the Company is required to obtain a license from a third party to sell any such product. In addition, upon meeting the foregoing limitation on revenue-sharing payments, the Company agreed to make continued revenue-sharing payments to CPRIT of less than 1% of net sales.

License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which, the Company acquired license to LSD 1. In exchange for the license, the Company issued 2% equity ownership in the Company based on a fully diluted basis at the effective date of the agreement and subject to certain adjustments specified in the agreement, granted revenue sharing rights on any resulting products or processes to commence on first commercial sale, and milestone payments based upon regulatory approval of any resulting product or process as well as on the second anniversary of first commercial sale.

Lease Agreement

The Company presently leases office and laboratory space under operating lease agreements on a month to month basis.

NOTE 7. FAIR VALUE OF FINANCIAL INSTRUMENTS

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, are used to measure fair value:

Level 1-Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3-Significant unobservable inputs including Decoy's own assumptions in determining fair value.

The Company issued preferred stock as part of the consideration transferred in its asset acquisition with a fair value of $4,302,000 as of November 12, 2025. This fair value is measured on a non-recurring basis. The valuation was estimated using a Monte Carlo simulation model and is classified as a level 3 measurement within the fair value hierarchy, primarily due to the use of significant unobservable inputs. The key inputs and assumptions used in the various scenarios for the fair value measurement are below:

	Inputs and assumptions
Term	0.5-4.5 years
Risk-free rate	3.6%
Estimated volatility	120.0%
Discount for lack of marketability	18.0%-32.0%

The Company believes the recorded values of its financial instruments, including cash and cash equivalents, accounts payable, preferred stock issued to Legacy Decoy debtholder and note payable approximate their fair values due to the short-term nature of these instruments.

NOTE 8. RELATED PARTY TRANSACTIONS

As of December 31, 2025, one officer/founder of the Company had an outstanding Demand Note in the principal amount of $55,555, plus accrued interest of approximately $13,000. This note accrues interest at 10% and has a maturity date of December 28, 2024. An agreement to exchange this note for Salarius Series B Preferred Stock, contingent upon Closing of the Merger, has been executed. As of December 31, 2025, one family member of an officer/founder of the Company had an outstanding Demand Note in the amount of $83,333, plus accrued interest of approximately $22,000 and an outstanding Promissory Note in the amount of $100,000, plus accrued interest of approximately $20,000. An agreement to exchange this note for Salarius Series B Preferred Stock, contingent upon Closing of the Merger, has been executed. During the second half of 2024 and first half of 2025, founders of the Legacy Decoy loaned Legacy Decoy approximately $140,000 through non- interest bearing, open-ended maturity notes. As of July 22, 2025 these notes were amended to have a maturity date in November 2026.

NOTE 9. STOCKHOLDERS' EQUITY

Common Stock Issuances

On November 11, 2025, Salarius entered into an underwriting agreement (the “Underwriting Agreement”) with Ladenburg Thalmann & Co. Inc., as the sole underwriter (the “Representative”), relating to the issuance and sale in a public offering (the “Offering”) of: (i) 209,528 shares of the Company’s common stock, par value $0.0001 per share (the “Common Stock”), (ii) pre-funded warrants to purchase up to 179,361 shares of Common Stock, (iii) Series A warrants to purchase up to 388,889 shares of Common Stock, (iv) Series B warrants to purchase up to 388,889 shares of Common Stock, and (v) up to 58,333 additional shares of Common Stock, Series A warrants to purchase up to an additional 58,333 shares of Common Stock and Series B warrants to purchase up to an additional 58,333 shares of Common Stock that may be purchased pursuant to a 45-day option to purchase additional securities granted to the Representative by the Company. The Representative exercised this option on November 11, 2025 for 55,477 shares of Common Stock, Series A warrants to purchase up to 58,333 shares of Common Stock and Series B warrants to purchase up to 58,333 shares of Common Stock. The combined public offering price of each share of Common Stock, together with the accompanying Series A warrants and Series B warrants, was $18, less underwriting discounts and commissions. The combined public offering price of each pre-funded warrant, together with the accompanying Series A warrants and Series B warrants, was $17.9988, less underwriting discounts and commissions. The Offering, including the additional shares of Common Stock, Series A warrants and Series B warrants sold pursuant to the exercise of the Representative’s option, closed on November 12, 2025.

On February 5, 2021,Salarius entered into an At the Market Offering Agreement ("ATM") with Ladenburg Thalmann & Co. Inc. Under this agreement the Company is able to issue and sell, from time to time, shares of its common stock. On February 5, 2021 and July 2, 2021, the Company filed prospectus supplements with the SEC to register the offering and sale of Common Stock having an aggregate offering price of up to $6.3 million and $25.0 million, respectively. During the twelve months ended December 31, 2025 and 2024, the Company sold 42,244 and 3,383 shares of common stock under the At the Market Offering Agreement with gross proceeds of $3 million and $1.7 million, respectively.

On December 12, 2024, we entered into a securities purchase agreement (the “ELOC Agreement”) with C/M Capital Master Fund, LP (the “Purchaser”). Pursuant to the ELOC Agreement, the Company issued and sold a total of 37,035 shares (the “Purchased Shares”) of common stock to the Purchaser at a weighted average exercise price of $128.76 for an aggregate purchase price of $4.8 million through March 27, 2026. These issuances and sales were made following written notice delivered by the Company to the Purchaser, directing the Purchaser to purchase the Purchased Shares. We also issued 370 shares of our common stock to the Purchaser as commitment shares pursuant to the terms of the ELOC Agreement.

Preferred Stock Issued to Legacy Decoy Stockholders and Debtholders

In connection with the Merger, the Company issued 877.709 shares of the Series A Preferred Stock and 796.306 shares of the Series B Preferred Stock to former Legacy Decoy stockholders and debtholders and reserved 45.098 shares of Series A Preferred Stock for assumed in-the-money options and warrants of Legacy Decoy. In connection with the adjustment to the conversion ratio in the certificate of designations for the Series A and Series B Preferred Stock triggered by the offering, the number of Company common shares underlying the issued and reserved shares of Series A and Series B Preferred Stock is 401,126. The shares of Series A Preferred Stock and Series B Preferred Stock are not convertible into Common Stock until such time as the Company’s stockholders approve such conversion in accordance with Nasdaq Rule 5635 and the approval of the Company’s initial listing application with Nasdaq.

Warrants

In connection with the Offering closed on November 12, 2025, Salarius issued pre-funded warrants to purchase up to 179,361 shares of Common Stock. All pre-funded warrants from this Offering were fully exercised as of December

31, 2025. The Company also issued Series A warrants to purchase up to 388,889 shares of Common Stock, Series B warrants to purchase up to 388,889 shares of Common Stock, and up to 58,333 additional shares of Common Stock, Series A warrants to purchase up to an additional 58,333 shares of Common Stock and Series B warrants to purchase up to an additional 58,333 shares of Common Stock that may be purchased pursuant to a 45-day option to purchase additional securities granted to the Representative by the Company. The Company also issued warrants to the Representative to purchase up to 22,218 shares of Common Stock at an exercise price of $27.90 (the "Representative Warrants"). The Representative Warrants are exercisable at any time and from time to time, in whole or in part, until November 11, 2030, and have substantially similar terms to the Series A warrants. All Series A warrants, Series B warrants and Representative Warrants are outstanding at December 31, 2025.

As of December 31, 2025, the Company had 481 outstanding warrants issued between 2020 and 2023, with exercise prices ranging from $2,970 to $42,552 per share.

As of December 31, 2025 and 2024, approximately 932,991 and 3,116 warrants remained outstanding, respectively.

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2023	**7,531**	$ 3,929
Expired	(4,415)	
Outstanding at December 31, 2024	**3,116**	6,162
Granted	916,805	
Assumed from Assets Acquisition	15,705	
Canceled	(2,526)	
Expired	(109)	
Outstanding at December 31, 2025	**932,991**	$ 26.06

The terms of the outstanding warrants require the Company, upon the consummation of any fundamental transaction to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume the Company's obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of the Company's common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the warrants could also impede the Company's ability to enter into certain transactions or obtain additional financing in the future.

NOTE 10. EQUITY-BASED COMPENSATION

Equity Incentive Plans

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards may be granted to the Company's employees, including officers, and to non-employee directors and consultants. The 2015 Plan expired in accordance with its terms in January 2025 and was replaced by a stockholder approved plan in February 2026.

During the twelve months ended December 31, 2025 and 2024, the Company awarded 0 and 117, respectively, stock options to its employees and directors, pursuant to the plan described above. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants of $0.1 million has been estimated with the following assumptions for the year ended December 31, 2025:

	2025
Risk-free interest rate	4.00%-4.61%
Volatility	82% - 123.31%
Expected life (years)	4.5 -6 years
Expected dividend yield	0.00 %

The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2025 and 2024:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at December 31, 2023	62	$ 34,243.20	7.13
Granted	117	$ 543.60	
Exercised	—	—	
Forfeited	(4)	—	
Expired	—	—	
Outstanding at December 31, 2024	175	$ 12,015.00	8.2
Exercisable at December 31, 2024	52	$ 36,550.80	6.17
Granted	—	$ —	
Options assumed from asset acquisition	13,548		
Exercised	—		
Forfeited	—		
Expired	—		
Outstanding at December 31, 2025	13,723	$ 480.70	7.51
Exercisable at December 31, 2025	10,216	$ 451.34	7.35

As of December 31, 2025 and 2024, there was approximately $1.1 million and $0.1 million of total unrecognized compensation cost, respectively, related to unvested stock options. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 0.47 years.

NOTE 11. INCOME TAX

The Company has no current or deferred tax expense due to its current year loss and its overall net operating loss position. A reconciliation of the federal statutory tax rate and the effective tax rates for the year ended December 31, 2025 and 2024 is as follows:

	Year Ended December 31, 2025		2024
	Amount	Percent	Percent
Federal Tax at Statutory Rate	(2,628,293.00)	21.00 %	21.00 %
State Taxes	-	— %	— %
Permanent	25,826.00	(0.21)%	(0.83)%
Credits	(27,915.00)	0.22 %	1.34 %
Valuation Allowance	2,630,478.00	(21.02)%	(21.51)%
Other	(96.00)	— %	— %
Effective Tax Rate	— %	— %	— %

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets were as follows:

	2025	2024
Capitalized R&D Expenses	$ 4,142,751	$ 4,565,699
Other Deferred Items	394,900	43,982
Stock Compensation	462,785	437,328
Net Operating Loss - US	11,963,371	8,349,314
R&D Credits	3,941,317	3,701,895
Deferred Revenue	881,229	—
Total gross deferred tax assets	**$ 21,786,353**	**$ 17,098,218**
Valuation Allowance	(21,786,353)	(17,098,218)
Net deferred tax assets	—	—

In assessing the realizability of the net deferred tax assets the Company considers all relevant positive and negative evidence to determine whether it is more likely than not that some portion of the deferred income tax will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to expiration of the net operation loss carryforwards. At December 31, 2025 and 2024 the Company has recorded a full valuation allowance against its net deferred tax assets of approximately $21, 786,000 and $17,098,000 respectively. The change in valuation allowance during the year ended 2025 was approximately $4,688,000.

At December 31, 2025, the Company had federal net operation loss (NOL) carryforwards of approximately $54.5 million. At December 31, 2025, the Company had federal research and development credit carryforwards of approximately $3.5 million. The federal net operating loss carryforwards begin to expire in 2028, losses generated in 2018 or later of $54.5 million will carry forward indefinitely. The federal credit carryforwards begin to expire in 2045. Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company may be subject to the net operating loss utilization provision of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation of the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital

during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2025 there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2009 and as such, tax years subject to potential tax examination could apply from that date. This is because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the 12 months ended December 31, 2025 and 2024.

NOTE 12. SEGMENT REPORTING

The Company has been concentrated on developing treatments for cancers caused by dysregulated gene expression. The current pipeline consists of two small molecule drugs: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat ("SP-2577"), a targeted protein inhibitor. (3) IMP^{3}ACT Platform, a single molecule can activate or inhibit multiple targets/receptors in an additive or synergistic manner to achieve superior or multi-indication efficacy. The Company does not have any revenue generating products.

For the years ended December 31, 2025 and December 31, 2024, the Company identified one operating and reportable segment relating to its operations. The Company defines its operating segment based on internally reported financial information that is regularly reviewed by the Chief Operating Decision Maker (the CODM), its Chief Executive Officer. The CODM reviews the segment's loss based on net loss reported on the consolidated statement of operations.

The Company's CODM views specific categories within research and development expenses and general and administrative expenses as significant given the direct correlation between cash burn as a pre-revenue company. The table below is a summary of the segment loss, including significant segment expenses:

	Year Ended December 31,	
	2025	**2024**
Expenses:		
Research and development:		
SP-3164	$ 56,297	$ 345,580
SP-2577	4,541	424,447
IMP^{3}ACT	307,332	-
Acquired in-process research and development asset	8,517,966	-
General and administrative:		
Professional services and Consulting	1,933,990	2,692,815
Personnel cost	1,089,669	1,472,811
Facility cost	704,157	798,663
Loss from operations	12,613,952	5,734,316
Interest income, net	95,472	158,539
Net loss	$ 12,518,480	$ 5,575,777

NOTE 13. SUBSEQUENT EVENTS

On March 5, 2026, the Company filed a Certificate of Amendment to the Company's amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect the 2026 Reverse Stock Split as of March 6, 2026. See Note 1 for a full discussion of the 2026 Reverse Stock Split.

On March 13, 2026, the Company received a written notice from the Nasdaq Hearings Panel (the “Hearings Panel”) granting the Company's request to continue its listing on The Nasdaq Stock Market. Previously, the Company had appealed a delisting determination issued by Nasdaq due to the Company's failure to maintain compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). Pursuant to the Hearings Panel's decision, the continued listing of the Company's securities is subject to the condition that the Company must demonstrate compliance with the Minimum Bid Price Requirement on or before March 20, 2026. In connection with its compliance plan, the Company completed a reverse stock split on March 6, 2026 and subsequently achieved a closing bid price of $7.47 on March 20, 2026, thereby demonstrating compliance with the Minimum Bid Price Requirement.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

As of December 31, 2025, our management, including our principal executive officer and principal financial officer, had evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) pursuant to Rule 13a-15(b) under the Exchange Act. Based upon and as of the date of the evaluation, our principal executive officer and principal financial officer concluded that information required to be disclosed is recorded, processed, summarized and reported within the specified periods and is accumulated and communicated to management, including our principal executive officer and principal financial officer, to allow for timely decisions regarding required disclosure of material information required to be included in our periodic SEC reports. Based on the foregoing, our management determined that our disclosure controls and procedures were effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

No change in our company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the framework in Internal Control—Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Item 9B. Other Information

During the three months ended December 31, 2025, no director or officer of the Company, nor the Company itself, 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

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders (the "2026 Proxy Statement"), pursuant to Regulation 14A of the Exchange Act of 1934, also referred to in this Annual Report on Form 10-K as our 2026 Proxy Statement, which we expect to file with the SEC no later than April 30, 2026.

Item 10. Directors, Executive Officers and Corporate Governance

The information required to be disclosed in Item 10 is hereby incorporated by reference to our 2026 Proxy Statement.

Item 11. Executive Compensation

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2026 Proxy Statement.

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

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2026 Proxy Statement.

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

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2026 Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2026 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements on page 87.

(a)(2) Financial Statement Schedules.

We have omitted these schedules because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of January 10, 2025, by and among the Registrant, Decoy Therapeutics Inc., Decoy Therapeutics MergerSub I, Inc. and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
2.2	Amendment No. 1 to the Agreement and Plan of Merger, dated as of March 28, 2025, by and among Salarius Pharmaceuticals, Inc., Decoy Therapeutics, Inc., Decoy Therapeutics MergerSub I, Inc. and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 28, 2025).
2.3	Amendment No. 2 to the Agreement and Plan of Merger, dated as of June 10, 2025, by and among Salarius Pharmaceuticals, Inc., Decoy Therapeutics, Inc., Decoy Therapeutics MergerSub I, Inc., and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 11, 2025).
2.4	Amendment No. 3 to the Agreement and Plan of Merger, dated as of July 18, 2025, by and among Salarius Pharmaceuticals, Inc., Decoy Therapeutics, Inc., Decoy Therapeutics MergerSub I, Inc., and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 21, 2025).
2.5	Amendment No. 4 to the Agreement and Plan of Merger, dated as of July 29, 2025, by and among Salarius Pharmaceuticals, Inc., Decoy Therapeutics, Inc., Decoy Therapeutics MergerSub I, Inc., and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2025).
2.6	Amendment No. 5 to the Agreement and Plan of Merger, dated as of July 29, 2025, by and among Salarius Pharmaceuticals, Inc., Decoy Therapeutics, Inc., Decoy Therapeutics MergerSub I, Inc., and Decoy Therapeutics MergerSub II, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 28, 2025).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2015).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on July 18, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).

3.3	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on October 14, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 14, 2022).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on June 14, 2024 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 14, 2024).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Salarius Pharmaceuticals, Inc., effective August 15, 2025 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 15, 2025).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Salarius Pharmaceuticals, Inc., effective January 8, 2026 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 8, 2026).
3.7	Form of Certificate of Designation of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 18, 2025).
3.8	Form of Certificate of Designation of Series B Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 2.3 to the Registrant's Current Report on Form 8-K filed with the SEC on September 18, 2025).
3.9	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Salarius Pharmaceuticals, Inc., effective March 6, 2026 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 5, 2026).
3.10	Amended and Restated Bylaws of the Registrant, effective July 19, 2019 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).
3.11	Amendment to the Amended and Restated Bylaws of the Registrant, effective April 1, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 1, 2022).
3.12	Second Amended and Restated Bylaws of the Registrant, effective January 8, 2026 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 8, 2026).
4.1	Form of Common Stock Certificate of Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's registration statement on Form S-1 (File No. 333-201276), as amended, filed January 13, 2015).
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.8 to the Registrant's S-1 (File No. 333-201276), as amended, filed February 6, 2020).
4.3	Common Stock Purchase Warrant dated February 11, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 12, 2020).
4.4	Form of Inducement Warrant dated December 11, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K/A filed with the SEC on December 11, 2020).
4.5	Form of 2021 Flex Warrants (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 1, 2021).

4.6	Form of Common Stock Purchase Warrant dated April 26, 2022 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 22, 2022).
4.7	Form of Placement Agent Warrants (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
4.8	Warrant Agency Agreement, dated November 12, 2025, by and between the Company and Equiniti Trust Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 11, 2025).
4.9*	Description of Registrant's Securities
4.10	Form of Series A Warrant (incorporated by reference to Exhibit 4.12 to the Company's Form S-1/A, as filed with the Securities and Exchange Commission on October 21, 2025).
4.11	Form of Series B Warrant (incorporated by reference to Exhibit 4.13 to the Company's Form S-1/A, as filed with the Securities and Exchange Commission on October 21, 2025).
4.12	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.9 to the Company's Form S-1/A, as filed with the Securities and Exchange Commission on October 21, 2025).
4.13	Form of Representative Warrant (incorporated by reference to Exhibit 4.10 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.1+	Form of Indemnification Agreement between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).
10.2+	Indemnification Agreement, dated February 20, 2024, between Salarius Pharmaceuticals, Inc. and David J. Arthur (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.3^	Exclusive License Agreement, dated August 3, 2011, between the University of Utah Research Foundation and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on February 14, 2019 (the "S-4")).
10.4^	Cancer Research Grant Contract, dated June 1, 2016, between the Cancer Prevention and Research Institute of Texas and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.3 to the S-4).
10.5+	Amended and Restated Executive Employment Agreement, dated February 5, 2019, between David J. Arthur and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the S-4).
10.6+	Amendment to Amended and Restated Executive Employment Agreement dated September 10, 2019, among David J. Arthur, the Registrant and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on September 16, 2019).
10.7+	Separation and Release Agreement, dated February 20, 2024, between David J. Arthur and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).

10.8+	Executive Employment Agreement, dated April 24, 2020, between Mark J. Rosenblum and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 29, 2020).
10.9+	Amendment to Executive Employment Agreement, dated February 20, 2024, between Mark J. Rosenblum and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.10+	Executive Employment Agreement by and between Frederick E. Pierce and Salarius Pharmaceuticals, Inc., dated November 18, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 19, 2025).
10.11+	Executive Employment Agreement, dated November 18, 2025, between Barbara Hibner and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on November 19, 2025).
10.12+	Executive Employment Agreement, dated November 18, 2025, between Peter Marschel. and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on November 19, 2025).
10.13+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 24, 2015).
10.14+	Notice of Stock Option Amendment, dated February 20, 2024, between David J. Arthur and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.15+	Amended and Restated Salarius Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 15, 2023).
10.16+	Salarius Pharmaceuticals, Inc., 2015 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 19, 2020)
10.17	At the Market Offering Agreement, dated February 5, 2021, between Salarius Pharmaceuticals, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 5, 2021).
10.18	Securities Purchase Agreement, dated April 22, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 22, 2022).
10.19	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
10.20	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
10.21	Securities Purchase Agreement, dated December 12, 2024, by and between Salarius Pharmaceuticals, Inc. and C/M Capital Master Fund, LP. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 13, 2024).

10.22	Registration Rights Agreement, dated December 12, 2024, by and between Salarius Pharmaceuticals, Inc. and C/M Capital Master Fund, LP (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 13, 2024).
10.23	Warrant Cancellation Agreement, dated as of January 10, 2025, by and among the Registrant and an Investor (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
10.24+	Amendment 1 to Consulting Agreement, effective February 20, 2024, by and between the Registrant and David J. Arthur (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2025).
10.25	Grant Agreement, dated September 9, 2021, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation).
10.26	Amendment 1 to Grant Agreement, dated August 29, 2023, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation).
10.24	Amendment 2 to Grant Agreement, dated February 26, 2025, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation).
10.28	Letter Agreement, dated January 31, 2023, by and between Decoy Therapeutics Inc. and Johnson & Johnson Innovation LLC.
10.39	Letter Agreement, dated July 28, 2023, by and between Decoy Therapeutics, Inc. and Johnson & Johnson Innovation LLC.
10.30	Letter Agreement, dated March 11, 2024, by and between Decoy Therapeutics, Inc. and Johnson & Johnson Innovation LLC.
10.31	Form of Decoy Note Conversion Agreement (incorporated by reference to Exhibit 10.32 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.32	Form of Decoy Series A Amended and Restated Note Conversion Agreement (incorporated by reference to Exhibit 10.33 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.33	Form of Decoy Series B Amended and Restated Note Conversion Agreement (incorporated by reference to Exhibit 10.34 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.34	Grant Agreement, dated September 9, 2021, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation) (incorporated by reference to Exhibit 10.26 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.35	Amendment 1 to Grant Agreement, dated August 29, 2023, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation) (incorporated by reference to Exhibit 10.27 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).
10.36	Amendment 2 to Grant Agreement, dated February 26, 2025, by and between Decoy Therapeutics, Inc. and The Gates Foundation (formerly known as the Bill & Melinda Gates Foundation) (incorporated by reference to Exhibit 10.28 to the Company's Form S-1, as filed with the Securities and Exchange Commission on October 21, 2025).

19.1	Salarius Pharmaceuticals, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2025).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Form S-1).
23.1*	Consent of Ernst & Young LLP
24.1*	Power of Attorney (see signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), 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	Salarius Pharmaceuticals, Inc. Clawback Policy (incorporated by reference to Exhibit 97 to the Registrant's Form 10-K filed with the SEC on March 22, 2024)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Schema Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

^ Exhibits and/or schedules or portions thereof have been omitted pursuant to Item 601(a)(5) Item 601(b)(10)((iv) of Regulation S-K and provided separately to the SEC pursuant to a request for confidential treatment.
+ Management contract or compensatory plans or arrangements.
* Filed herewith.
** Furnished herewith

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

March 31, 2026

DECOY THERAPEUTICS INC.

By: /s/ Frederick E. Pierce
Frederick E. Pierce
Chief Executive Officer

Each of the undersigned officers and directors of Decoy Therapeutics Inc., hereby constitutes and appoints Frederick E. Pierce and Mark J. Rosenblum, their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Annual Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this annual report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated

SIGNATURE	***TITLE***	***DATE***
/s/ Frederick E. Pierce *Frederick E. Pierce*	*Chief Executive Officer and Director* *(Principal Executive Officer)*	March 31, 2026
/s/ Mark J. Rosenblum *Mark J. Rosenblum*	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 31, 2026
/s/ William K. McVicar *William K. McVicar*	*Chairman of the Board of Directors*	March 31, 2026
/s/ David J. Arthur *David J. Arthur*	*Director*	March 31, 2026
/s/ Tess Burleson *Tess Burleson*	*Director*	March 31, 2026
/s/ Arnold Hanish *Arnold Hanish*	*Director*	March 31, 2026
/s/ Paul Lammers *Paul Lammers*	*Director*	March 31, 2026
/s/ Jonathan Lieber *Jon Lieber*	*Director*	March 31, 2026

Exhibit 4.9

DESCRIPTION OF THE COMPANY'S SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

The summary of general terms and provisions of the capital stock of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.) (the "Company") set forth below does not purport to be complete and is subject to and qualified by reference to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), the Amended and Restated Bylaws (the "Bylaws"), and the Certificates of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock and the Series B Non-Voting Convertible Preferred Stock (collectively, the "Certificates of Designation," and together with the Certificate of Incorporation and the Bylaws, the "Charter Documents"), each of which is included as an exhibit to the Company's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and incorporated by reference herein. For additional information, please read the Charter Documents and the applicable provisions of the Delaware General Corporation Law (the "DGCL").

Authorized Capital Stock

The Company is authorized to issue up to 110,000,000 shares, of which (i) 100,000,000 have been designated common stock, par value $0.0001 per share ("Common Stock"), and (ii) 10,000,000 have been designated preferred stock, par value $0.0001 per share ("Preferred Stock"). Of the authorized Preferred Stock, the Company has designated 924 shares of Series A Non-Voting Convertible Preferred Stock (the "Series A Preferred Stock") and 797 shares of Series B Non-Voting Convertible Preferred Stock (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Designated Preferred Stock"), the terms of which are described below.

Common Stock

Voting Rights

The holders of shares of Common Stock have the exclusive power to vote on all matters presented to the Company's stockholders unless Delaware law or the certificate of designation for an outstanding series of Preferred Stock gives the holders of that series of Preferred Stock the right to vote on certain matters. Each holder of shares of Common Stock is entitled to one vote per share.

When a quorum is present at any meeting, the vote of the holders of a majority of the voting power of the Common Stock entitled to vote and present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which by express provision of the Charter Documents or by law, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors are elected by a plurality of the voting power of the shares present in person or represented by proxy and entitled to vote on the election of directors at a meeting at which a quorum is present, and stockholders are not entitled to cumulate their votes for the election of directors.

Dividend Rights

Subject to any prior rights of any Preferred Stock then outstanding, the holders of shares of Common Stock are entitled to receive dividends ratably out of funds legally available, when and if declared by the Company's board of directors (the "Board").

No Preemptive or Similar Rights

The Common Stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

If the Company becomes subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to the stockholders would be distributable ratably among the holders of the Common Stock and any participating Preferred Stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of Preferred Stock. Neither the Series A Preferred Stock nor the Series B Preferred Stock has a fixed-dollar liquidation preference; however, upon any liquidation, dissolution or winding-up of the Company, holders of the Designated Preferred Stock are entitled to receive, prior to any distribution to holders of junior securities, a cash amount per share equal to the as-if-converted value.

Designated Preferred Stock

In connection with the Company's merger with Decoy Therapeutics Inc. (the "Merger"), which closed on November 12, 2025, the Company issued shares of Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock. The rights and preferences of each series are set forth in the applicable Certificate of Designation filed with the Secretary of State of the State of Delaware. The following is a summary of the material terms of each series.

Series A Non-Voting Convertible Preferred Stock

Dividends. Holders of Series A Preferred Stock are entitled to receive dividends equal to, on an as-if-converted-to-Common-Stock basis, and in the same form as, dividends actually paid on shares of Common Stock.

Voting Rights. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of a majority of the then-outstanding shares of Series A Preferred Stock: (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Series A Certificate of Designation; (b) amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or Bylaws in a manner that adversely alters or changes the preferences, rights, privileges or powers of the Series A Preferred Stock; (c) issue further shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock; (d) authorize, create or issue classes or series of equity securities other than junior securities; (e) authorize, create and/or issue any funded indebtedness (other than indebtedness already incurred); (f) sell or transfer, other than in the ordinary course of business, mortgage, assign, pledge, lease, grant a security interest in, or encumber any of the Company's assets; or (g) enter into any agreement with respect to any of the foregoing.

Conversion. Each share of Series A Preferred Stock is convertible into shares of Common Stock at the then-prevailing conversion ratio, subject to (i) stockholder approval of the conversion in accordance with Nasdaq Rule 5635 and (ii) Nasdaq approval of the Company's initial listing application (collectively, the "Conversion Conditions"). Until the Conversion Conditions are satisfied, no shares of Series A Preferred Stock may be converted. Following satisfaction of the Conversion Conditions, each share of Series A Preferred Stock will be automatically converted into such number of shares of Common Stock as is determined by the then-prevailing conversion ratio. The initial conversion ratio was 1,000 shares of Common Stock per share of Series A Preferred Stock. However, the conversion ratio is subject to anti-dilution adjustment: if the Company conducts any financing at an effective price per underlying share of Common Stock below the initial issuance price of $10.50, the conversion ratio will be reset proportionally, with the denominator subject to a floor price of $3.75 per underlying share. The Company's November 12, 2025 financing (the "November 2025 Financing") triggered the floor price, and accordingly the conversion ratio was reset to 2,800 shares of Common Stock per share of Series A Preferred Stock. Thereafter, the Company effected a 1-for-12 reverse stock split, which further adjusted the conversion ratio to 233.33 shares of Common Stock per share of Series A Preferred Stock effective March 6, 2026. No single holder may convert shares to the extent such conversion would result in such holder (together with its affiliates) beneficially owning more than 4.99% of the then-outstanding Common Stock (the "Beneficial Ownership Limitation"), subject to such holder's right to increase this limit to 9.99% upon 61 days' prior notice. In no event may the Beneficial Ownership Limitation exceed 19.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion.

Liquidation. The Series A Preferred Stock does not have a fixed-dollar liquidation preference; however, upon any liquidation, dissolution or winding-up of the Company, holders of Series A Preferred Stock are entitled to receive, prior to any distribution to holders of junior securities, a cash amount per share equal to the as-if-converted value.

No Listing. The Series A Preferred Stock is not listed on any national securities exchange and is not registered under the Securities Act of 1933, as amended.

Series B Non-Voting Convertible Preferred Stock

The Series B Preferred Stock is identical in all material respects to the Series A Preferred Stock, except for the following additional terms:

Mandatory Redemption. Fifty percent (50%) of the net proceeds received by the Company from any post-closing drawdowns and/or sales under its at-the-market equity program with Ladenburg Thalmann & Co. Inc. or equity line of credit with C/M Capital Master Fund, LP must be used to redeem outstanding shares of Series B Preferred Stock at the redemption price until all Series B Preferred Stock is fully redeemed.

Optional Redemption. The Company has the option to redeem all or any portion of the outstanding Series B Preferred Stock at any time following the Merger closing upon seven (7) days' prior written notice to the holders. The redemption price per share equals the initial issuance price multiplied by 83.33 (reflecting the initial conversion ratio, as adjusted for the Company's 1-for-12 reverse stock split effected on March 6, 2026), subject to adjustment.

Optional Conversion. Following satisfaction of the Conversion Conditions, holders of Series B Preferred Stock may convert any or all of their shares into Common Stock at the then-prevailing

conversion ratio, subject to the Beneficial Ownership Limitation. After the one-year anniversary of the satisfaction of the Conversion Conditions, any remaining shares of Series B Preferred Stock will automatically convert into Common Stock at the then-prevailing conversion ratio.

The conversion ratio applicable to the Series B Preferred Stock is subject to the same anti-dilution adjustment and reverse stock split adjustments as the Series A Preferred Stock, and is currently 233.33 shares of Common Stock per share of Series B Preferred Stock, effective March 6, 2026.

Liquidation. The Series B Preferred Stock does not have a fixed-dollar liquidation preference; however, upon any liquidation, dissolution or winding-up of the Company, holders of Series B Preferred Stock are entitled to receive, prior to any distribution to holders of junior securities, a cash amount per share equal to the as-if-converted value.

Undesignated Preferred Stock

The Board has the authority, without further action by the Company's stockholders, to designate and issue shares of Preferred Stock in one or more series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by the Company's stockholders. The existence of authorized but unissued shares of undesignated Preferred Stock would enable the Board to render more difficult or to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or other means.

Anti-Takeover Provisions in Charter Documents

Certain provisions of the Charter Documents, which are summarized below, may have the effect of delaying, deferring or preventing another person from acquiring control of the Company. These provisions may discourage takeovers, coercive or otherwise, and are also designed, in part, to encourage persons seeking to acquire control of the Company to negotiate first with the Board. The Company believes that the benefits of increased protection of the Company's potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire the Company because negotiation of these proposals could result in an improvement of their terms. These provisions include the following:

Board of Directors Vacancies

Pursuant to the Charter Documents, the Board may fill vacant directorships. In addition, directors may only be removed for cause and only upon the affirmative vote of at least sixty-six and two-thirds percent of the voting power of outstanding voting stock. In addition, the number of directors constituting the Board may be set only by a resolution adopted by a majority vote of the Board. These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes in control or management of the Company and will make it more difficult to change the composition of the Board, which will promote continuity of management.

Classified Board

The Charter Documents provide that the Board is classified into three classes of directors, with each class serving three-year staggered terms. A third-party may be discouraged from making a tender offer or otherwise attempting to obtain control of the Company as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board of directors.

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Stockholder Action; Special Meeting of Stockholders

Pursuant to Section 228 of the DGCL, any action required to be taken at any annual or special meeting of the stockholders may be taken without a meeting, without prior notice and without a vote if a consent or consents in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of stock entitled to vote thereon were present and voted, unless the Certificate of Incorporation provides otherwise. The Certificate of Incorporation provides that stockholders may not take action by written consent but may only take action at annual or special meetings of stockholders. As a result, a holder controlling a majority of the Company's capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of stockholders called in accordance with the Charter Documents. The Bylaws provide that special meetings of the stockholders may be called only upon a resolution approved by a majority of the total number of directors that the Company would have if there were no vacancies. These provisions might delay the ability of the Company's stockholders to force consideration of a proposal or for stockholders controlling a majority of the Company's capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

The Bylaws provide advance notice procedures for stockholders seeking to bring business before the Company's annual meeting of stockholders or to nominate candidates for election as directors at the Company's annual meeting of stockholders. The Bylaws specify certain requirements regarding the form and content of a stockholder's notice and prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting. These provisions might preclude stockholders from bringing matters before the Company's annual meeting of stockholders or from making nominations for directors at the Company's annual meeting of stockholders if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

No Cumulative Voting

The DGCL provides that stockholders are not entitled to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. The Certificate of Incorporation does not provide for cumulative voting.

Amendment of Charter Provisions and Bylaws

The Charter Documents provide that the Bylaws may be adopted, amended, altered or repealed by either (i) a vote of a majority of the total number of directors of the Board or (ii) in addition to any other vote otherwise required by law, the affirmative vote of the holders of at least sixty-six and two-thirds percent of the voting power of all of the then outstanding shares of capital stock entitled to vote generally in the election of directors.

The Charter Documents also provide that the provisions of the Certificate of Incorporation relating to the management of the business, the Board, director liability, indemnification and forum selection may only be amended, altered, changed or repealed by the affirmative vote of the holders of at least sixty-six and two-thirds percent of the voting power of all of the Company's outstanding

shares of capital stock entitled to vote generally in the election of directors, voting together as a single class.

Issuance of Undesignated Preferred Stock

The Board has the authority, without further action by the Company's stockholders, to designate and issue shares of Preferred Stock with rights and preferences, including super voting, special approval, dividend or other rights or preferences on a discriminatory basis. The existence of authorized but unissued shares of undesignated Preferred Stock would enable the Board to render more difficult or to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or other means.

Business Combinations with Interested Stockholders

The Company is subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination, such as a merger, with an interested stockholder (i.e., subject to certain exceptions, a person or group owning 15% or more of the corporation's voting stock) for a period of three years following the date the person became an interested stockholder, unless (with certain exceptions) the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner.

Forum Selection

The Charter Documents provide that unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for:

- any derivative action or proceeding brought on behalf of the Company;
- any action asserting a claim of breach of a fiduciary duty owed by any director, officer, or other employee of the Company to the Company or the Company's stockholders;
- any action asserting a claim of breach of a fiduciary duty owed by any director, officer, or other employee of the Company to the Company or its stockholders; and
- any action asserting a claim against the Company governed by the internal affairs doctrine.

In each such case, subject to such Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. The Charter Documents also provide that any person or entity purchasing or otherwise acquiring any interest in shares of the Company's capital stock will be deemed to have notice of, and to have consented to, this forum selection provision.

Although these provisions benefit the Company by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of increasing the costs of and discouraging lawsuits against the Company's directors, officers, employees and agents. The enforceability of similar exclusive forum provisions in other companies' charters has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could rule that this provision in the Certificate of Incorporation is inapplicable or unenforceable. For example, the choice of forum provisions summarized above are not intended to, and would not, apply to suits

brought to enforce any liability or duty created by the Exchange Act of 1934, as amended, or other claim for which the federal courts have exclusive jurisdiction. Additionally, there is uncertainty as to whether the Company's choice of forum provisions would be enforceable with respect to suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), or other claims for which the federal courts have concurrent jurisdiction, and in any event stockholders will not be deemed to have waived the Company's compliance with federal securities laws and the rules and regulations thereunder.

Listing

The Common Stock is listed on the Nasdaq Capital Market under the symbol "DCOY." Prior to January 8, 2026, the Common Stock traded under the symbol "SLRX."

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-201816) pertaining to the 2014 Equity Incentive Plan, 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of Decoy Therapeutics Inc. (formerly known as Flex Pharma, Inc.);
(2) Registration Statement (Form S-8 Nos. 333-210283, 333-216534, 333-223499, 333-230104, 333-246310, 333-262896, and 333-269801) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(3) Registration Statement (Form S-3 No. 333-252169) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(4) Registration Statement (Form S-1 No. 333-235879) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(5) Registration Statement (Form S-1MEF No. 333-236306) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(6) Registration Statement (Form S-3 No. 333-265535) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(7) Registration Statement (Form S-3 No. 333-266589) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(8) Registration Statement (Form S-3 No. 333-272249) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(9) Registration Statement (Form S-1 No. 333-283828) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);
(10) Registration Statement (Form S-3 No. 333-289646) of Decoy Therapeutics Inc. (formerly known as Salarius Pharmaceuticals, Inc.);

of our report dated March 31, 2026, with respect to the consolidated financial statements of Decoy Therapeutics Inc. included in this Annual Report (Form 10-K) of Decoy Therapeutics Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Houston, Texas
March 31, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Frederick E. Pierce , certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Decoy Therapeutics Inc.;
2. based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. the registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. the registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2026

By: /s/ Frederick E. Pierce
Name: Frederick E. Pierce
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Rosenblum, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Decoy Therapeutics Inc.;
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.

Dated: March 31, 2026

By: /s/ Mark Rosenblum
Name: Mark Rosenblum
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the year ended December 31, 2025 of Decoy Therapeutics Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frederick E. Pierce, Chief Executive 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:

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

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2026

By: /s/ Frederick E. Pierce
Name: Frederick E. Pierce
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 on Form 10-K for the year ended December 31, 2025 of Decoy Therapeutics Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Rosenblum, 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:

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

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2026

By: /s/ Mark Rosenblum
Name: Mark Rosenblum
Title:Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)