

As filed with the Securities and Exchange Commission on July 24, 2024.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

41-1505029

(I.R.S. Employer
Identification No.)

Soligenix, Inc.
29 Emmons Drive, Suite B-10
Princeton, New Jersey 08540
(609) 538-8200

(Address, including zip code, and telephone number, including area code,
of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
Soligenix, Inc.

29 Emmons Drive, Suite B-10
Princeton, New Jersey 08540
(609) 538-8200

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

with copies to:

Driscoll R. Ugarte, Esq.
Duane Morris LLP
5100 Town Center Circle, Suite 400
Boca Raton, Florida 33486
(561) 962-2100

Approximate date of commencement of proposed sale to the public: From time to time, at the discretion of the selling stockholders, after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 ☐
Non-accelerated filer ☒

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 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The selling stockholders shall not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus

Subject to Completion, Dated July 24, 2024



**Up to 1,054,688 Shares of Common Stock
Issuable Upon the Exercise of Previously Issued Common Warrants**

This prospectus relates to the resale from time to time by certain selling stockholders named herein (the "Selling Stockholders") of up to 1,054,688 shares of common stock par value \$0.001 per share ("Common Stock") of Soligenix, Inc. (the "Company," "us" or "we"), issuable upon exercise of Warrants to Purchase Shares of Common Stock (the "July 2024 Warrants"). The July 2024 Warrants were issued pursuant to that certain Warrant Inducement Agreement dated as of July 9, 2024, by and among the Company and the Selling Stockholders (the "Warrant Inducement Agreement"). The July 2024 Warrants entitle holders to purchase shares of our Common Stock at an exercise price of \$6.00 per share for a period of five years from issuance. Such shares of Common Stock underlying the July 2024 Warrants are collectively referred to herein as the "Resale Shares." We are registering the Resale Shares on behalf of the Selling Stockholders, to be offered and sold from time to time, to satisfy certain registration rights that we have granted to the Selling Stockholders pursuant to the Warrant Inducement Agreement.

The Selling Stockholders may resell or dispose of the Resale Shares to or through underwriters, broker-dealers, agents, or through any other means described in the section of this prospectus entitled "Plan of Distribution." The Selling Stockholders will bear the commissions and discounts, if any, attributable to the sale or disposition of the Resale Shares. We will bear all costs, expenses and fees in connection with the registration of the Resale Shares. We will not receive any of the proceeds from the sale of the Resale Shares by the Selling Stockholders.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "SNGX." On July 19, 2024, the last reported sale price of our Common Stock on the Nasdaq Capital Market was \$6.07 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 7 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 24, 2024.

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ABOUT THIS PROSPECTUS

This prospectus is part of a resale registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the “SEC”).

This prospectus includes important information about us, the securities being offered and other information you should know before investing in our securities. You should also read and consider information in the documents we have referred you to in the sections of this prospectus entitled “Where You Can Find More Information.”

You should rely only on the information contained in this prospectus (as supplemented and amended). We have not authorized anyone to provide you with different information. We take no responsibility for, and can provide no assurances as to the reliability of, any other information that others may give you. The information contained in this prospectus (and in any supplement or amendment to this prospectus) are accurate only as of their respective dates, regardless of the time of delivery of this prospectus, any applicable prospectus supplement, or any sale of a security. We urge you to read carefully this prospectus (as supplemented and amended), before deciding whether to invest in any of the Common Stock being offered.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled “Where You Can Find More Information.”

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “Soligenix,” “the Company,” “we,” “us,” “our” and similar references refer to Soligenix, Inc., a corporation organized under the laws of the State of Delaware, and its subsidiaries on a consolidated basis.

We are not making an offer or sale of our Common Stock in any jurisdiction where such offer or sale is not permitted. Neither we nor any of our representatives are making any representation to you regarding the legality of an investment in our Common Stock by you under applicable laws. We urge you to consult with your own advisors as to legal, tax, business, financial and related aspects of an investment in our Common Stock.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, including the information presented under the headings “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements and Industry Data and Market Information” in this prospectus and the historical financial statements and the notes thereto included elsewhere in this prospectus. You should pay special attention to the information contained under the caption titled “Risk Factors” in this prospectus, before deciding to buy our securities.

Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: Specialized BioTherapeutics and Public Health Solutions.

Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin sodium), a novel photodynamic therapy, utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma (“CTCL”). With agreement from the European Medicines Agency (“EMA”) on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early stage disease, we are targeting to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026. Upon successful completion of the second Phase 3 study, called “FLASH2” (Fluorescent Light Activated Synthetic Hypericin 2), regulatory approval will be sought to support potential commercialization worldwide.

Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, and our first-in-class Innate Defense Regulator (“IDR”) technology, dusquetide (SGX942 and SGX945), for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer and aphthous ulcers in Behçet’s Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID 19 (caused by SARS-CoV 2). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (“NIAID”), the Biomedical Advanced Research and Development Authority and the Defense Threat Reduction Agency.

Recent Developments

On June 23, 2023, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”) stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) (the “Minimum Bid Price Rule”) because our Common Stock failed to maintain a minimum closing bid price of \$1.00 for 30 consecutive trading days.

On December 21, 2023, we received written notice from Nasdaq stating that we had not complied with the Minimum Bid Price Rule and indicating that our Common Stock would be suspended from trading on Nasdaq unless we requested a hearing before a hearings panel by December 28, 2023. On March 26, 2024, we had an oral hearing with a Nasdaq Hearings Panel to appeal the delisting determination, which stayed the trading suspension of our Common Stock pending a final written decision by the Nasdaq Hearings Panel and expiration of any additional extension period granted by the panel following the hearing.

We effected a 1-for-16 reverse stock split on June 5, 2024 in order to regain compliance with the Minimum Bid Price Rule. Since the reverse stock split, the closing price for the Common Stock has been above \$1.00 per share.

On July 24, 2024, we received a letter from the Nasdaq confirming that we had regained compliance with the Minimum Bid Price Rule. Accordingly, the Nasdaq Hearings Panel determined to continue the listing of our Common Stock and closed the matter.

As of July 19, 2024, there were 2,280,108 shares of Common Stock issued and outstanding. Of the outstanding shares, 2,279,440 shares of Common Stock were held by non-affiliates of the Company (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the Common Stock are affiliates). The closing price for the Common Stock on July 19, 2024 was \$6.07 per share; consequently, the market value for our total listed securities and publicly held shares was \$13,840,256 and \$13,836,201, respectively. As of March 31, 2024, we had cash and cash equivalents of \$7,091,548, working capital of \$607,499 and total liabilities of \$7,290,013, of which over 41.1% was owed under our convertible debt facility. In the near term, we will need to obtain significant capital through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to continue to fund our operations. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all, particularly in light of our current stock price and liquidity.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

Specialized BioTherapeutics Product Candidates*

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
HyBryte™	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 trial completed; demonstrated statistical significance in primary endpoint in March 2020 (Cycle 1) and demonstrated continued improvement in treatment response with extended treatment in April 2020 (Cycle 2) and October 2020 (Cycle 3); New drug application ("NDA") submitted to the U.S. Food and Drug Administration ("FDA") December 2022; FDA refusal to file letter received February 2023; second Phase 3 trial based upon EMA-accepted protocol targeted to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026; discussions continue with FDA on modifying the development path to adequately address FDA's preference for a longer duration comparative study over a placebo-controlled trial
SGX302	Mild-to-Moderate Psoriasis	Positive proof-of-concept demonstrated in a small Phase 1/2 pilot study; Phase 2a protocol and Investigation New Drug ("IND") clearance received from the FDA; Phase 2a study remains ongoing having demonstrated biological effect in Cohort 1 and clinically meaningful benefit in Cohort 2
SGX942†	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial results announced December 2020: the primary endpoint of median duration of severe oral mucositis ("SOM") did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group; analyzed full dataset from Phase 3 study and designing a second Phase 3 clinical trial; continued development contingent upon identification of partnership

SGX945	Aphthous Ulcers in Behçet's Disease	Phase 2a protocol and IND clearance received from the FDA; Phase 2a study to be initiated in the second half of 2024
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Public Health Solutions†

Soligenix Product Candidate	Indication	Stage of Development
ThermoVax®	Thermostability of vaccines for Ricin toxin, Ebola, and Marburg viruses	Pre-clinical
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1a, 1b, and 1c trials completed, safety and neutralizing antibodies for protection demonstrated
SGX943	Therapeutic against Emerging Infectious Diseases	Pre-clinical

† Contingent upon continued government contract/grant funding or other funding source.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009.

Our principal executive offices are located at 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200. Our corporate website address is www.soligenix.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities.

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our Common Stock held by non-affiliates exceeds \$250 million as of the prior June 30, or (2) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our Common Stock held by non-affiliates exceeds \$700 million as of the prior June 30.

THE OFFERING

Shares of Common Stock Offered By the Selling Stockholders:	Up to 1,054,688 Resale Shares
Common Stock outstanding prior to this offering:	2,280,108 shares of Common Stock
Terms of the offering:	The Selling Stockholders will determine when and how they will dispose of any Resale Shares.
Use of proceeds:	We will not receive any proceeds from the sale of the Resale Shares by the Selling Stockholders.
Risk factors:	Investing in our Common Stock involves significant risks. Before deciding whether to invest in our Common Stock, please read the information contained in this prospectus, including under the heading "Risk Factors" on page 7 of this prospectus.
Nasdaq Capital Market Symbol:	"SNGX"

Unless otherwise indicated, the number of shares of Common Stock to be outstanding after this offering is based on 2,280,108 shares of Common Stock outstanding as of July 19, 2024. The number of shares of Common Stock outstanding after this offering excludes:

- 1,054,688 shares of Common Stock issuable upon the exercise of outstanding July 2024 Warrants at a weighted average price of \$6.00 per share, of which warrants to purchase 1,054,688 shares are exercisable as of July 19, 2024;
- 4,566 shares of Common Stock issuable upon the exercise of outstanding warrants (other than the July 2024 Warrants) at a weighted average price of \$6.40 per share, of which warrants to purchase 4,566 shares are exercisable as of July 19, 2024;
- 56,699 shares of Common Stock issuable upon the exercise of outstanding options at a weighted average exercise price of \$84.65 per share, of which options to purchase 23,959 shares of Common Stock are vested as of July 19, 2024;
- 5,051,513 shares of Common Stock available for future issuance under our 2015 Equity Incentive Plan as of July 19, 2024; and
- shares issuable upon the conversion of \$2,059,309 of principal and \$9,080 of accrued interest as of July 19, 2024 under convertible promissory notes, which may be converted at \$27.20 per share.

Unless otherwise indicated, all information in this prospectus gives effect to the 1-for-16 reverse stock split effectuated on June 5, 2024.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties that you should understand before making an investment decision. These risks include, but are not limited to, the following:

Risks Related to our Business

- We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts or not be able to repay certain convertible notes.
- Our losses from operations, negative cash flows, and shareholders' equity of approximately \$768,000 as of March 31, 2024 raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.
- The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2023 contains an explanatory paragraph relating to our ability to continue as a going concern.
- If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.
- We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.
- Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.
- There may be unforeseen challenges in developing our product candidates, including in the area of biodefense
- We are dependent on government funding, which is inherently uncertain, for the success of our public health business segment operations.
- The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility.
- If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.
- If we are not able to maintain or secure agreements with third parties for pre-clinical and clinical trials of our product candidates on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.
- The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.
- Even if approved, our products will be subject to extensive post-approval regulation.
- Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.
- We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.
- Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.
- Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.
- Federal and/or state health care reform initiatives could negatively affect our business.
- We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.
- We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.
- We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.
- We may not be able to compete with our larger and better-financed competitors in the biotechnology industry.
- Competition and technological change may make our product candidates and technologies less attractive or obsolete.
- Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.
- Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.
- Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

- We may not be able to utilize all of our net operating loss carryforwards.
- Global pathogens could have an impact on financial markets, materials sourcing, patients, governments and population (e.g. COVID-19).

Risks Related to our Intellectual Property

- We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.
- We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.
- If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

Risks Related to Technology and Intellectual Property

- Our strategy includes an increasing dependence on technology in our operations. If any of our key technology fails, our business could be adversely affected.
- A cybersecurity incident could negatively impact our business and our relationships with our employees, service providers, patients, clinical study sites and government agencies.

Risks Related to this Offering

- The price of our Common Stock may be highly volatile.
- If we fail to meet Nasdaq's listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market and negatively impact our ability to raise capital.
- Investors may suffer substantial dilution related to issued options and convertible promissory notes.
- Our shares of Common Stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.
- We do not currently intend to pay dividends on our Common Stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our Common Stock.
- Upon our dissolution, our stockholders may not recoup all or any portion of their investment.
- The issuance of our Common Stock pursuant to the terms of the asset purchase agreement with Hy Biopharma may cause dilution and the issuance of such shares of Common Stock, or the perception that such issuances may occur, could cause the price of our Common Stock to fall.

- Repayment of certain convertible notes, if they are not otherwise converted, will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness.
- The issuance of shares of Common Stock upon conversion of certain convertible notes could substantially dilute shareholders' investments and could impede our ability to obtain additional financing.
- Our Board of Directors can, without stockholder approval, cause preferred stock to be issued on terms that adversely affect holders of our Common Stock.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before investing in our securities, you should consider carefully the risks and uncertainties discussed below. You also should carefully consider each of the following risks, together with all other information set forth in this prospectus, including our consolidated financial statements and the related notes, before deciding to buy our securities. Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, cash flows and results of operations. If that occurs, the trading price of our Common Stock could decline materially, and you could lose all or part of your investment.

The risks included in this prospectus are not the only risks we face. We may experience additional risks and uncertainties not currently known to us, or as a result of developments occurring in the future. Conditions that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, cash flows and results of operations, and our ability to pay distributions to stockholders.

This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements and Industry Data and Market Information" for information relating to these forward-looking statements.

Risks Related to our Business

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts.

We have experienced significant losses since inception and, at March 31, 2024, had an accumulated deficit of approximately \$227,619,503. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2024, we had \$7,091,548 in cash and cash equivalents available, and as of July 19, 2024 we had \$12,281,699 in cash and cash equivalents available. Without additional funding, based on our projected budgetary needs and funding from existing contracts and grants over the next year, we expect to be able to maintain the current level of our operations through the 1st half of 2025.

In September 2014, we entered into a contract with the NIH for the development of RiVax[®] to protect against exposure to ricin toxin that would provide up to \$24.7 million of funding in the aggregate over six years if options to extend the contract are exercised by the NIH. In 2017, we were awarded two separate grants from the NIH of approximately \$1.5 million each to support our pivotal Phase 3 trials of HyBryte[™] for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer. In December 2020, we were awarded Direct to Phase II SBIR grant from NIAID of approximately \$1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and EVD vaccine candidates in conjunction with the CoVaccine HT[™] adjuvant. Our biodefense grants have an overhead component that allows us an

agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. As of March 31, 2024, we had approximately \$700,000 in awarded grant funding available.

Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through March 31, 2024, we have expended approximately \$120.1 million developing our current product candidates for pre-clinical research and development and clinical trials. We currently expect to spend approximately \$5.5 million for the year ending December 31, 2024 in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements, of which approximately \$0.3 million is expected to be reimbursed through our existing government grants.

We have no control over the resources and funding U.S. government agencies may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If U.S. government agencies do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results.

Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the Common Stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

Our losses from operations and negative cash flows as of March 31, 2024 raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.

We have concluded that substantial doubt exists about our ability to continue as a going concern for the 12 months following the issuance of the financial statements for the quarter ended March 31, 2024. As of March 31, 2024, we had cash and cash equivalents of \$7,091,548 and current liabilities of \$7,210,888. As of the issuance date of the financial statements for the quarter ended March 31, 2024, we believed that we have sufficient resources available to support our development activities and business operations and timely satisfy our obligations as they come due through the first half of 2025. We do not have sufficient cash and cash equivalents as of July 19, 2024 to support our operations for at least the 12 months following July 24, 2024.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, and potentially amending the loan agreement with Pontifax Medison Finance to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce our liabilities; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that we will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about our ability to continue as a going concern. If none of these alternatives are available, or if available, are not available

on satisfactory terms, we will not have sufficient cash resources and liquidity to fund our business operations for at least 12 months following the issuance of the financial statements for the quarter ended March 31, 2024. The failure to obtain sufficient capital on acceptable terms when needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2023 contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2023 includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to obtain the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

- we may not be able to maintain our current research and development schedules;
- we may be unable to secure procurement contracts on beneficial economic terms or at all from the U.S. government or others for our biodefense products;
- we may encounter problems in clinical trials; or
- the technology or product may be found to be ineffective or unsafe, or may fail to obtain marketing approval.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may be unable to develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to

commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

- it is not economical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- we are not able to manufacture the product reliably;
- others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a late-stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates in our two active business segments, Specialized BioTherapeutics and Public Health Solutions. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this prospectus and also include:

- our ability to obtain additional funding to develop our product candidates;
- our ability to repay existing debt in accordance with its terms;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our product candidates through all phases of clinical development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidates in the U.S. and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our dependence on third-party contract manufacturing organizations to supply or manufacture our products;

- our dependence on contract research organizations to conduct our clinical trials;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government contracts and grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

Our business is subject to very stringent federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years, is uncertain as to outcome, and requires the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials.

We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product (for example, the FDA may not recognize fast track designation upon an NDA submission, resulting in no priority review and subjecting us to longer potential review times than originally anticipated). Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include product recalls and suspension or withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasures for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government's biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the U.S. and internationally have the capability to test animals with ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense

companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

We are dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants and contracts we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

In December 2020, we entered into a loan and security agreement with Pontifax Medison Finance (the "Loan and Security Agreement"), that is secured by a lien covering substantially all of our assets, other than our intellectual property and licenses for intellectual property. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any material portion of our assets, incurring additional indebtedness, engaging in mergers or acquisitions, changing foreign subsidiary voting rights, repurchasing shares, paying dividends or making other distributions, making certain investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our Common Stock. The lender could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the Loan and Security Agreement or based upon our insolvency. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our Common Stock to decline.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or anticipate having internal manufacturing capabilities.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to

procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to be able to develop, produce, secure regulatory approval of and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We rely on third parties for pre-clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We rely on academic institutions, hospitals, clinics and other third-party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and/or oversee our pre-clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and/or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice ("cGMP") or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially

viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any product that we develop will depend on a number of factors, including:

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA for each of our products;
- reimbursement policies of government and third-party payors;
- effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and

- unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

We do not have extensive experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to successfully market and sell any of our products, the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships will be required. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

Initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If any of our product candidates cause serious adverse events or undesirable side effects:

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority

over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for HyBryte™ in the U.S. and Europe, and RiVax ® in the U.S., we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or EMA may subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Federal and/or state health care reform initiatives could negatively affect our business.

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that were separately billed at that time. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from New York University, Yeda Research and Development Company Ltd., the University of Texas Southwestern Medical Center, the University of British Columbia, and George B. McDonald, MD as well as sublicense agreement from VitriVax for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See "Business – Patents and Other Proprietary Rights" for a description of our license agreements.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force or enter into commercialization agreements with other companies. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with aggregate limits of liability of \$10 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks. We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may not be able to compete with our larger and better financed competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as

governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete with our existing and future competitors, which could lead to the failure of our business.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See “Business – The Drug Approval Process.”

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We currently have 15 employees and we depend upon these employees, in particular Dr. Christopher Schaber, our President and Chief Executive Officer, to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We may be unable to effectively manage and operate our business, and our business may suffer, if we lose the services of our employees.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

During recent years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.

Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the “FDIC”) as receiver. Despite subsequent actions taken by the U.S. Department of the Treasury, the U.S. Federal Reserve and the FDIC to ensure that all depositors of SVB had access to all of their cash deposits following the closure of SVB, uncertainty and liquidity concerns in the broader financial services industry remain.

We maintain cash balances at a third-party financial institution in excess of the FDIC insurance limit. Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired to the extent the financial institution with which we maintain cash balances faces liquidity constraints or failures. Any material decline in our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in significant disruptions to our business, any of which could have material adverse impacts on our operations and liquidity. There is no guarantee that the U.S. Department of Treasury, the U.S. Federal Reserve and the FDIC will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

We may not be able to utilize all of our net operating loss carryforwards.

The State of New Jersey’s Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss (“NOL”) carryforwards to other New Jersey-based corporate taxpayers. We sold 2022, 2021 and 2020 New Jersey NOL carryforwards, resulting in the recognition of \$1,767,803 and \$1,154,935 of income tax benefit, net of transaction costs during the years ended December 31, 2023 and 2022, respectively. The Company sold its 2022 New Jersey NOLs and has recorded a receivable of \$606,606 which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheet for the year ended December 31, 2023. We have not yet completed the sale of our 2023 New Jersey NOL carryforwards but may do so in the future. If there is an unfavorable change in the State of New Jersey’s Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our NOL carryforwards or if we are unable to find a suitable buyer to utilize our New Jersey NOL carryforwards to the extent the NOLs expire before we are able to utilize them against our taxable income, our cash taxes may increase which may have an adverse effect on our financial condition.

Global pathogens that could have an impact on financial markets, materials sourcing, patients, governments and population (e.g. COVID-19).

Global pathogens (e.g., SARS-CoV-2, the pathogen responsible for COVID-19) could cause an impact on financial markets and therefore repercussions to our operating business, including but not limited to, the sourcing of materials for our product candidates, manufacture of supplies for our preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for our trials due to such things as quarantines, our conduct of patient monitoring and clinical trial data retrieval at investigational study sites.

The impacts of outbreaks are highly uncertain and cannot be predicted, and we cannot provide any assurance that any outbreak will not have a material adverse impact on our operations or future results or filings with regulatory health authorities. The extent of the impact to us, if any, will depend on future developments, including actions taken to contain the pathogen.

Risks Related to our Intellectual Property

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our near and long-term prospects depend in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been the subject of much litigation. Any patents we own or license, now or in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office (the "PTO") regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patent applications publish or patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented

proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our Common Stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to

avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Technology and Intellectual Property

Our strategy includes an increasing dependence on technology in our operations. If any of our key technology fails, our business could be adversely affected.

Our operations are increasingly dependent on technology. Our information technology systems are critical to our ability to develop our products and otherwise operating our business. Problems with the operation of the information or communication technology systems we use could adversely affect, or temporarily disable, all or a portion of our operations. Further, any systems failures could impede our ability to timely collect and report financial results in accordance with applicable laws.

A cybersecurity incident could negatively impact our business and our relationships with our employees, service providers, patients, clinical study sites and government agencies.

We use information technology and operational technology assets, including computer and information networks, in substantially all aspects of our business operations. We also use mobile devices, social networking and other online activities to connect with our employees, service providers, patients, clinical study sites and government agencies. Such uses give rise to cybersecurity risks, including security breach, espionage, system disruption, theft and inadvertent release of information. Our business involves the storage and transmission of numerous classes of sensitive and/or confidential information and intellectual property, including clinical trial participants' personal information, private information about employees and financial and strategic information about us and our business partners. If we fail to assess and identify cybersecurity threats, we may become increasingly vulnerable to such threats. Additionally, while we have implemented measures to prevent security breaches and cyber incidents, our preventive measures and incident response efforts may not be entirely effective. Also, the regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and constantly changing requirements. This changing regulatory landscape may cause increasingly complex compliance challenges, which may increase our compliance costs. Any failure to comply with these changing security and privacy laws and regulations could result in significant penalties, fines, legal challenges and reputational harm. The theft, destruction, loss, misappropriation, or release of sensitive and/or confidential information or intellectual property, or interference with our information technology systems or the technology systems of third parties on which we rely, could result in business disruption, negative publicity, brand damage, violation of privacy laws, loss of confidence, potential liability and competitive disadvantage.

Risks Related to This Offering

The number of shares being registered for resale is significant in relation to the number of our outstanding shares of Common Stock.

We have filed a registration statement of which this prospectus is a part to register the shares offered hereunder for sale into the public market by the Selling Stockholders. These shares represent a large number of shares of our Common Stock, and if sold in the market all at once or at about the same time, could depress the market price of our Common Stock during the period the registration statement remains effective and could also affect our ability to raise equity capital.

The price of our Common Stock may be highly volatile.

The market price of our securities, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and the price of our Common Stock may be volatile in the future due to a wide variety of factors, including:

- announcements by us or others of results of pre-clinical testing and clinical trials;
- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- failure of our Common Stock to continue to be listed or quoted on a national exchange or market system, such as Nasdaq or the New York Stock Exchange;
- our quarterly operating results and performance;
- developments or disputes concerning patents or other proprietary rights;
- mergers or acquisitions;
- litigation and government proceedings;
- adverse legislation;
- changes in government regulations;
- our available working capital;
- economic and other external factors; and
- general market conditions.

Since January 1, 2023, the closing stock price of our Common Stock has fluctuated between a high of \$122.40 per share to a low of \$2.00 per share. On July 19, 2024, the last reported sale price of our Common Stock on The Nasdaq Capital Market was \$6.07 per share. The fluctuation in the price of our Common Stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of Common Stock and warrants by us, as well as potential sale of Common Stock by the holders of warrants, options and convertible promissory notes, could have an adverse effect on the market price of our shares.

If we fail to meet Nasdaq's listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market and negatively impact our ability to raise capital.

Companies trading on Nasdaq, such as our Company, must be reporting issuers under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and must meet the listing requirements in order to maintain the listing of Common Stock on The Nasdaq Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

If our Common Stock is delisted from Nasdaq, it will have material negative impact on the actual and potential liquidity of our securities, as well as material negative impact on our ability to raise future capital. If, for any reason, Nasdaq should delist our Common Stock from trading on its exchange and we are unable to obtain listing on another national securities exchange or take action to restore our compliance with the Nasdaq continued listing requirements, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our Common Stock;
- the market price of our Common Stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our securities;
- the number of market makers in our Common Stock;
- the availability of information concerning the trading prices and volume of our Common Stock; and
- the number of broker-dealers willing to execute trades in shares of our Common Stock.

Shareholders may suffer substantial dilution related to issued stock warrants, options and convertible promissory notes.

As of July 19, 2024, we have a number of agreements or obligations that may result in dilution to investors. These include:

- 1,054,688 shares of Common Stock issuable upon the exercise of outstanding July 2024 Warrants at a weighted average price of \$6.00 per share, of which warrants to purchase 1,054,688 shares are exercisable as of July 19, 2024;
- 4,566 shares of Common Stock issuable upon the exercise of outstanding warrants (other than the July 2024 Warrants) at a weighted average price of \$6.40 per share, of which warrants to purchase 4,566 shares are exercisable as of July 19, 2024;
- 56,699 shares of Common Stock issuable upon the exercise of outstanding options at a weighted average exercise price of \$84.65 per share, of which options to purchase 23,959 shares of Common Stock are vested as of July 19, 2024;
- 5,051,688 shares of Common Stock available for future issuance under our 2015 Equity Incentive Plan as of July 19, 2024; and
- shares issuable upon the conversion of \$2,059,309 of principal and \$9,080 of accrued interest as of July 19, 2024 under convertible promissory notes, which may be converted at \$27.20 per share.

We also have an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our Common Stock to our directors, employees and consultants. To the extent that warrants, options or convertible promissory notes are exercised or converted, our stockholders will experience dilution and our stock price may decrease.

Additionally, the sale, or even the possibility of the sale, of the shares of Common Stock underlying these warrants, options and convertible promissory notes could have an adverse effect on the market price for our securities or on our ability to obtain future financing.

Our shares of Common Stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our Common Stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our Common Stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

We do not currently intend to pay dividends on our Common Stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our Common Stock.

We have never declared or paid cash dividends on our Common Stock and do not anticipate paying any cash dividends to holders of our Common Stock in the foreseeable future. Consequently, our stockholders must rely on sales of their Common Stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our Common Stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Upon our dissolution, our stockholders may not recoup all or any portion of their investment.

In the event of our liquidation, dissolution or winding-up, whether voluntary or involuntary, the proceeds and/or our assets remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the holders of Common Stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of Common Stock, or any amounts, upon such a liquidation, dissolution or winding-up. In this event, our stockholders could lose some or all of their investment.

The issuance of our Common Stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of Common Stock, or the perception that such issuances may occur, could cause the price of our Common Stock to fall.

On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma Inc. (“Hy Biopharma”) granted us an option to purchase certain assets, properties and rights (the “Hypericin Assets”) related to the development of Hy Biopharma's synthetic hypericin product candidate for the treatment of CTCL, which we refer to as HyBryte™, from Hy Biopharma. In exchange for the option, we paid \$50,000 in cash and issued 288 shares of Common Stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the Asset Purchase Agreement, we initially paid \$275,000 in cash and issued 12,328 shares of Common Stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma. Also, on September 3, 2014, we entered into a Registration Rights Agreement with Hy Biopharma, pursuant to which we may be required to file a registration statement with the SEC. In March 2020, we issued 130,413 shares of Common Stock at a value of \$5,000,000 (based upon an effective per share price of \$38.40

as a result of HyBryte™ demonstrating statistically significant treatment response in the Phase 3 clinical trial. We will be required to issue up to \$5.0 million worth of our Common Stock (subject to a cap equal to 19.9% of our issued and outstanding Common Stock) in the aggregate, if HyBryte™ is approved for the treatment of CTCL by either the FDA or the EMA.

The number of shares that we may issue under the Asset Purchase Agreement will fluctuate based on the market price of our Common Stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our Common Stock to fall.

We may ultimately issue all, some or none of the additional shares of our Common Stock that may be issued pursuant to the Asset Purchase Agreement. We are required to register any shares issued pursuant to the Asset Purchase Agreement for resale under the Securities Act. After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the Asset Purchase Agreement could result in substantial dilution to the interests of other holders of our Common Stock. Additionally, the issuance of a substantial number of shares of our Common Stock pursuant to the Asset Purchase Agreement, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Repayment of certain convertible notes, if they are not otherwise converted, will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness.

Our ability to pay the principal of and/or interest on the convertible notes issued pursuant to the loan and security agreement with Pontifax Medison Finance (the “Convertible Notes”) depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Convertible Notes or other future indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt and implement one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional debt financing or equity financing on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes or other future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Convertible Notes.

The issuance of shares of Common Stock upon conversion of the Convertible Notes could substantially dilute shareholders’ investments and could impede our ability to obtain additional financing.

The Convertible Notes are convertible into shares of our Common Stock and give the holders an opportunity to profit from a rise in the market price of our Common Stock such that conversion or exercise thereof could result in dilution of the equity interests of our shareholders. As of July 19, 2024, there was \$2,059,309 of principal and \$9,080 of accrued interest outstanding under the Convertible Notes. We have no control over whether the holders will exercise their right to convert their Convertible Notes. While the Convertible Notes are convertible at \$27.20 per share, we cannot predict the market price of our Common Stock at any future date, and therefore, cannot predict whether the Convertible Notes will be converted. We also may choose to reduce the conversion price of the Convertible Notes, which would likely cause the Convertible Notes to be converted into a significant amount of our Common Stock and reduce our liabilities. The existence and potentially dilutive impact of the Convertible Notes may prevent us from obtaining additional financing in the future on acceptable terms, or at all.

Our Board of Directors can, without stockholder approval, cause preferred stock to be issued on terms that adversely affect holders of our Common Stock.

Under our Certificate of Incorporation, our Board of Directors is authorized to issue up to 230,000 shares of preferred stock, of which none are issued and outstanding as of the date of this prospectus. Also, our Board of

Directors, without stockholder approval, may determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares. If our Board of Directors causes shares of preferred stock to be issued, the rights of the holders of our Common Stock would likely be subordinate to those of preferred holders and therefore could be adversely affected. Our Board of Directors' ability to determine the terms of preferred stock and to cause its issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire a majority of our outstanding Common Stock. Preferred shares issued by our Board of Directors could include voting rights or super voting rights, which could shift the ability to control the Company to the holders of the preferred stock. Preferred stock could also have conversion rights into shares of our Common Stock at a discount to the market price of our Common Stock, which could negatively affect the market for our Common Stock. In addition, preferred stock would have preference in the event of liquidation of the Company, which means that the holders of preferred stock would be entitled to receive the net assets of the Company distributed in liquidation before the holders of our Common Stock receive any distribution of the liquidated assets.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND
INDUSTRY DATA AND MARKET INFORMATION**

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. These forward-looking statements are often identified by words such as “may,” “should,” “would,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue,” “plan,” “potential” and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

- uncertainty as to whether our product candidates will be sufficiently safe and effective to support regulatory approvals;
- uncertainty inherent in developing therapeutics and vaccines, and manufacturing and conducting preclinical and clinical trials;
- our ability to obtain future financing or funds when needed, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- our ability to secure government grants or contracts to support our vaccine development;
- our ability to maintain our listing on Nasdaq and meet Nasdaq's listing requirements;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- maintenance and progression of our business strategy;
- the possibility that our products under development may not gain market acceptance;
- our expectations about the potential market sizes and market participation potential for our product candidates may not be realized;
- our expected revenues (including sales, milestone payments and royalty revenues) from our product candidates and any related commercial agreements of ours may not be realized;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to timely address any regulatory issues that have arisen or may arise in the future;
- competition existing today or that may arise in the future, including the possibility that others may develop technologies or products superior to our products;
- the effect that global pathogens could have on financial markets, materials sourcing, service providers, patients, clinical study sites, governments and population (e.g. COVID 19); and

- other factors, including those “Risk Factors” beginning on page 7 of this prospectus.

You should also consider carefully the statements under the section titled “Risk Factors” in this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Industry Data and Market Information

This prospectus contains estimates, projections and other statistical data made by independent parties and by us relating to market size and growth, the potential value of government procurement contracts, the incidence of certain medical conditions and other industry data. These data, to the extent they contain estimates or projections, involve a number of subjective assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. While we believe that the data from these industry publications and other reports are generally reliable, we have not independently verified the accuracy or completeness of such data in all instances. These and other factors could cause results to differ materially from those expressed in these publications and reports.

We have provided estimates of the potential worldwide market or value of potential government procurement contracts and grants for certain of our product candidates. These estimates are based on a number of factors, including our expectation as to the number of patients with a certain medical condition that would potentially benefit from a particular product candidate, the current costs of treating patients with the targeted medical condition, our expectation that we will be able to demonstrate to the FDA's satisfaction in our clinical trials that the product candidate is safe and effective, our belief that our product candidate would, if approved, have an assumed treatment cost per patient, historic values of government procurement contracts for vaccines, and our expectation of the dosage of the product candidate. While we have determined these estimates based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. Among these factors are the following: (1) there is no assurance that the product candidate will prove to be safe and effective or will ultimately be approved for sale by the FDA; (2) any FDA approval of the product candidate may contain restrictions on its use or require warning labels; (3) third party payors may not be willing to provide reimbursement for the product candidate at the assumed price per patient; (4) the government may not be willing to procure our vaccine candidates in amounts or at costs similar to its historic procurement activities; (5) the dosage that ultimately may be approved may be different from the assumed dosage; and (6) doctors may not adopt the product candidate for use as quickly or as broadly as we have assumed. It is possible that the ultimate market for a product candidate or value of procurement contracts will differ significantly from our expectations due to these or other factors. As a result of these and other factors, investors should not place undue reliance on such estimates.

USE OF PROCEEDS

This prospectus relates to the Resale Shares that may be offered and sold from time to time by the Selling Stockholders. We will not receive any proceeds upon the sale of the Resale Shares by the Selling Stockholders pursuant to this prospectus; however, we may receive proceeds from the exercise of the July 2024 Warrants, if such warrants are exercised. Assuming the exercise of all the July 2024 Warrants for cash, we will receive gross proceeds of \$6,328,128. We will use the net proceeds from the exercise of the July 2024 Warrants to fund our research and development and commercialization activities, and for general corporate and working capital purposes, which may include, among other things, working capital, product development and/or commercialization, acquisitions, capital expenditures, repayment of debt and other business opportunities.

DIVIDEND POLICY

We have not paid cash dividends on our Common Stock, and we do not anticipate that we will declare or pay dividends on our Common Stock in the foreseeable future. Payment of dividends, if any, is within the sole discretion of our Board of Directors and will depend, among other factors, upon our earnings, capital requirements and our operating and financial condition. To the extent we have any earnings, we likely will retain earnings to pay down debt, or expand corporate operations and not use such earnings to pay dividends.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "SNGX." The following table sets forth the high and low sales prices per share of our Common Stock for the periods indicated, as reported by The Nasdaq Capital Market.

Period	Price Range	
	High	Low
Year Ended December 31, 2022:		
First Quarter	\$ 218.40	\$ 139.20
Second Quarter	\$ 192.00	\$ 91.20
Third Quarter	\$ 240.00	\$ 103.20
Fourth Quarter	\$ 175.20	\$ 93.60
Year Ended December 31, 2023:		
First Quarter	\$ 129.60	\$ 28.00
Second Quarter	\$ 67.20	\$ 10.24
Third Quarter	\$ 11.84	\$ 6.72
Fourth Quarter	\$ 32.00	\$ 6.08
Year Ending December 31, 2024:		
First Quarter	\$ 19.20	\$ 8.96
Second Quarter	\$ 14.88	\$ 2.50

Our stock is listed on The Nasdaq Capital Market under the symbol "SNGX". The Nasdaq Capital Market prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions. On July 19, 2024, the last reported price of our Common Stock quoted on The Nasdaq Capital Market was \$6.07 per share.

Unregistered Sales of Equity Securities

We issued (1) a vendor 337 shares of fully vested Common Stock with a fair value of \$148.80 per share on February 7, 2022; (2) a vendor 401 shares of fully vested Common Stock with a fair value of \$124.80 per share on May 6, 2022; (3) a vendor 229 shares of fully vested Common Stock with a fair value of \$218.40 per share on August 5, 2022; (4) a vendor 105 shares of fully vested Common Stock with a fair value of \$115.20 per

share on October 4, 2022; (5) a vendor 321 shares of fully vested Common Stock with a fair value of \$156.00 per share on November 7, 2022; (6) issued a total of 9,139 shares of Common Stock to two lenders upon conversion of approximately \$100,000 of principal under promissory notes at a conversion price of \$10.88 on January 3, 2024; (7) issued a total of 27,651 shares of Common Stock to two lenders upon conversion of approximately \$154,840 of principal under promissory notes at a conversion price of \$5.60 on April 15, 2024 and (8) the July 2024 Warrants to the Selling Stockholders on July 10, 2024 in exchange for the Selling Stockholders agreeing to exercise for cash existing warrants to purchase 703,125 shares of our Common Stock at an exercise price of \$6.00 per share (which includes the \$0.125 charge for the July 2024 Warrants in compliance with the Nasdaq rules).

The issuance of Common Stock as described above was exempt under Section 4(a)(2) of the Securities Act of 1933, as amended. The recipients are knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about us or had adequate access to information about us. The vendors represented to the Company that the vendors are not “consultants” for purposes of Nasdaq Listing Rule 5635(c).

Transfer Agent

Shares of our Common Stock are issued in registered form. Equiniti Trust Company, LLC, 48 Wall Street, Floor 23, New York, NY 10005 (Telephone: (718) 921-8200; Facsimile: (718) 765-8719) is the registrar and transfer agent for shares of our Common Stock.

Holders of Common Stock

As of July 19, 2024, there were 182 holders of record of our Common Stock. As of such date, 2,280,108 shares of our Common Stock were issued and outstanding.

Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. The maximum number of shares of our Common Stock available for issuance under the 2005 Equity Incentive Plan is 1,250 shares. In April 2015, our Board of Directors approved the 2015 Equity Incentive Plan, which was approved by stockholders on June 18, 2015. The maximum number of shares of Common Stock available for issuance under the 2015 Equity Incentive Plan is 6,000,000 shares.

The following table sets forth certain information, as of December 31, 2023, with respect to the following compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance:

- all compensation plans previously approved by our security holders; and
- all compensation plans not previously approved by our security holders.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders ⁽¹⁾	56,609	\$ 90.58	5,943,590
Equity compensation plans not approved by security holders	—	—	—
Total	56,609	\$ 90.58	5,943,590

(1) Includes our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. Our 2005 Equity Incentive Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes and our unaudited consolidated interim financial statements and their notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements and Industry Data and Market Information."

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: Specialized BioTherapeutics and Public Health Solutions.

Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin sodium), a novel photodynamic therapy utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"). With agreement from the European Medicines Agency ("EMA") on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early stage disease, we are targeting to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026. Upon successful completion of the second Phase 3 study, called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2), regulatory approval will be sought to support potential commercialization worldwide.

Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, and our first-in-class IDR technology, dusquetide (SGX942 and SGX945), for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer and aphthous ulcers in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs, targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of the vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority and the Defense Threat Reduction Agency.

An outline of our business strategy follows:

- Following agreement from the EMA on the key design components for the second confirmatory Phase 3 placebo-controlled FLASH2 (Florescent Light Activated Synthetic Hypericin 2) clinical trial of HyBryte™ in CTCL and positive primary endpoint results from the first Phase 3 FLASH study, initiate the FLASH2 study, while at the same time, continuing discussions with the U.S. Food and Drug Administration ("FDA") on potential modifications to the development path to adequately address their feedback.
- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.
- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 in the treatment of oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.
- Expanding development of dusquetide under the research name SGX945 into Behçet's Disease with the conduct of a Phase 2a clinical trial, where previous studies with dusquetide in oral mucositis have validated the biologic activity in aphthous ulcers induced by chemotherapy and radiation.
- Continue development of our heat stabilization platform technology, ThermoVax®, in combination with programs for RiVax® (ricin toxin vaccine), and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses and multivalent combinations), with U.S. government and non-governmental organization funding support.
- Continue to apply for and secure additional government funding for each of our Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.
- Pursue business development opportunities for pipeline programs, as well as explore all strategic alternatives, including but not limited to merger/acquisition strategies.
- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements, we believe that the following accounting policies are those most critical to the assumptions and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenues include revenues generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when we incur reimbursable internal expenses that are related to the government contracts and grants.

We also record revenue from contracts with customers in accordance with Accounting Standards Codification Topic 606 ("ASC 606"), *Revenue From Contracts with Customers*. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Certain amounts received from or billed to customers in accordance with contract terms are deferred and recognized as future performance obligations are satisfied. All amounts earned under contracts with customers other than sales-based royalties are classified as license revenues. Sales-based royalties under our license agreements would be recognized as royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue.

Research and Development Costs

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contract and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for

services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- contract research organizations (“CROs”) in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites active and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of stock options and to accrue for clinical trials in process that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Changes in Results of Operations

Three Months Ended March 31, 2024 Compared to March 31, 2023

For the three months ended March 31, 2024 we had a net loss of \$1,915,327 as compared to a net loss of \$1,046,109 for the same prior year period, representing increased net loss of \$869,218 or 83%. This increase in net loss was primarily due to the recognition of an income tax benefit during the three months ended March 31, 2023 with no corresponding income tax benefit recognized during the three months ended March 31, 2024.

Our revenues and associated costs incurred relate to government contracts, grants and subawards received to support the development of SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; development of CiVax™, our vaccine candidate for the prevention of COVID-19, and evaluation of HyBryte™ for expanded treatment in patients with early stage CTCL. For the three months ended March 31, 2024, we had revenues of \$117,029 as compared to \$257,178 for the same prior year period, representing a decrease of \$140,149 or 54%. We also incurred costs related to those revenues for the three months ended March 31, 2024 and 2023 of \$117,029 and \$226,040, respectively, representing a

decrease of \$109,011 or 48%. Our gross profit for the three months ended March 31, 2024 was zero or 0% of total revenues, as compared to a gross profit of \$31,138 or 12% of total revenues for the same period in 2023, representing a decrease of \$31,138 or 100%. The decrease in revenue and gross profit during the three months ended March 31, 2024 was primarily related to the conclusion of higher margin grants associated with the development of SGX943 and CiVax™ and a decrease in revenue associated with the zero margin grant for the HyBryte™ investigator initiated study.

Research and development expenses were \$1,095,040 for the three months ended March 31, 2024 as compared to \$946,451 for the same period in 2023, representing an increase of \$148,589 or 16%. The increase was primarily due to an increase in preliminary costs associated with the anticipated initiation of our Phase 2 study in Behçet's Disease and the second confirmatory Phase 3 CTCL trial.

General and administrative expenses were \$1,022,051 for the three months ended March 31, 2024, as compared to \$1,235,376 for the same period in 2023, representing a decrease of \$213,325 or 17%. The decrease in general and administrative expenses for the three months ended March 31, 2024 was primarily attributable to a reduction in legal and professional fees associated with a reverse stock split of our issued and outstanding shares of Common Stock during the three months ended March 31, 2023.

The amendment to the convertible debt financing agreement with Pontifax Medison Finance ("Pontifax") – see Note 4 to our quarterly financial statements found elsewhere in this prospectus –, resulted in the extinguishment of the original convertible debt for accounting purposes. We elected to account for the amended convertible debt using the fair value option, which requires us to record changes in fair value as a component of other income or expense. The fair value of the convertible debt as of March 31, 2024 was \$2,996,136, which resulted in the recognition of \$165,382 of other income from the change in the fair value of the convertible debt on our accompanying condensed consolidated statements of operations during the three months ended March 31, 2024. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

Interest expense, net for the three months ended March 31, 2024 was (\$28,842) as compared to \$103,568 for the same period in 2023, representing a decrease of \$132,410 or 128%. The decrease is primarily associated with the reduction in interest resulting from the repayment of \$6M of the convertible debt principal balance.

Year Ended December 31, 2023 Compared to 2022

For the year ended December 31, 2023, we had a net loss of \$6,140,730 as compared to a net loss of \$13,798,339 for the prior year, representing decreased net loss of \$7,657,609 or 55%. The decrease in net loss is primarily attributed to decreases in operating expenses and interest expense as well as an increase in other income. For the year ended December 31, 2023, we had revenues of \$839,359 as compared to \$948,911 for the prior year, representing a decrease of \$109,552 or 12%. The decrease in revenues was primarily a result of the recognition of licensing revenue in 2022 partially offset by an increase in grant revenue during 2023.

We incurred costs related to contract and grant revenues in the year ended December 31, 2023 and 2022 of \$742,048 and \$550,822, respectively, representing an increase of \$191,226 or 35%. The increase in costs was primarily the result of an increase in costs relating to the HyBryte™ investigator-initiated study.

Our gross profit for the year ended December 31, 2023 was \$97,311 or 12% of total revenues as compared to \$398,089 or 42% of total revenues for the prior year, representing a decrease of \$300,778 or 76%. The decrease in gross profit was primarily the result of the recognition of higher margin licensing revenue in 2022 and the lower margin grant revenue associated with the HyBryte™ investigator-initiated study during 2023.

Research and development expenses decreased by \$4,631,390 or 58% to \$3,312,699 for year ended December 31, 2023 as compared to \$7,944,089 for the prior year. The decrease in research and development spending for the year ended December 31, 2023 was primarily related to the decrease in manufacturing and regulatory costs associated with the HyBryte™ NDA filing.

General and administrative expenses decreased by \$2,210,352 or 33%, to \$4,482,552 for the year ended December 31, 2023, as compared to \$6,692,904 for the prior year. This decrease is primarily related to a reduction in legal and consulting expenses.

The amendment to the convertible debt financing agreement with Pontifax Medison Finance ("Pontifax") – see Note 5 to our audited financial statements found elsewhere in this prospectus –, resulted in the extinguishment of the original convertible debt for accounting purposes. We elected to account for the amended convertible debt using the fair value option, which requires us to record changes in fair value as a component of other income or expense. The fair value of the convertible debt on the date of the amendment was approximately \$3,304,000, which resulted in the recognition of a loss on extinguishment of approximately \$394,000 on our accompanying consolidated statements of operations during the year ended December 31, 2023. The fair value of the convertible debt as of December 31, 2023 was approximately \$3,260,934, which resulted in the recognition of \$43,066 of other income from the change in the fair value of the convertible debt on our accompanying consolidated statements of operations during the year ended December 31, 2023. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

Total other expense for the year ended December 31, 2023 was \$210,593 as compared to \$714,370 of total other expense for the prior year, reflecting a decrease of \$503,777 or 71%. The decrease in total other expense was primarily associated with the reduction in interest resulting from the repayment of a portion of the convertible debt principal balance and higher interest income earned on cash balances.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused NOL carryforwards to other New Jersey-based corporate taxpayers. We sold 2022, 2021 and 2020 New Jersey NOL carryforwards resulting in the recognition of income tax benefits, net of transaction costs of \$1,767,803 and \$1,154,935 during the years ended December 31, 2023 and 2022, respectively. We sold our 2022 New Jersey NOLs and have recorded a receivable of \$606,606 which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheet for the year ended December 31, 2023. We have not sold our 2023 New Jersey NOL carryforwards but may do so in the future. We will continue to explore opportunities to sell unused NOL carryforwards for the year ended December 31, 2023. However, there can be no assurance as to the continuation or magnitude of this program in future years.

Business Segments

We maintain two active business segments for the years ended December 31, 2023 and 2022: Specialized BioTherapeutics and Public Health Solutions.

The Specialized BioTherapeutics business segment had revenue of \$395,124 for the year ended December 31, 2023 as compared to \$31,929 for the year ended December 31, 2022, representing an increase of \$363,195 or 100%. The increase was due to increased reimbursable development activity under the grant to support the investigator-initiated study of HyBryte™ for expanded treatment in patients with early stage CTCL.

Revenues for the Public Health Solutions business segment for the year ended December 31, 2023 were \$444,235 as compared to \$916,982 for the year ended December 31, 2022, representing a decrease of \$472,747 or 52%. The decrease in revenues was primarily the result of the recognition of licensing revenue in 2022 and the conclusion of the grant associated with the development of SGX943.

Loss from operations for the Public Health Solutions business segment for the year ended December 31, 2023 was \$36,531 as compared to income from operations of \$26,612 for the year ended December 31, 2022, representing a decrease of \$63,143 or 237%. The loss for the year ended December 31, 2023 is attributable to the recognition of licensing revenue in 2022 and additional expenses incurred due to the expiration of grants and contracts. Loss from operations for the Specialized BioTherapeutics business segment for the year ended December 31, 2023 was \$2,812,303 as compared to \$7,614,988 for the year ended December 31, 2022,

representing a decreased loss of \$4,802,685 or 63%. This decreased loss is primarily attributed to the decrease in manufacturing and regulatory costs associated with the HyBryte™ NDA filing.

Financial Condition and Liquidity

Cash and Working Capital

As of March 31, 2024, we had cash and cash equivalents of \$7,091,548 as compared to \$8,446,158 as of December 31, 2023, representing a decrease of \$1,354,610 or 16%. As of March 31, 2024, we had working capital of \$607,499 as compared to working capital of \$3,355,212 as of December 31, 2023, representing a decrease of \$2,747,713 or 82%. The decrease in cash and cash equivalents was primarily related to cash used in operating activities during the three months ended March 31, 2024. The decrease in working capital is primarily the result of the reclassification of approximately \$1 million of the convertible debt balance from a non-current liability as of December 31, 2023 to a current liability as of March 31, 2024 (resulting from the amendment to the loan and security agreement with Pontifax – see Note 4 to our quarterly financial statements found elsewhere in this prospectus), and cash used in operating activities during the three months ended March 31, 2024.

Based on our operating budget, current rate of cash outflows, cash on hand, and proceeds from government contract and grant programs, we believe that we have sufficient resources available to support our development activities and business operations and timely satisfy our obligations as they become due through the first quarter of 2025. We do not have sufficient cash and cash equivalents as of the date of filing this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of our Common Stock via an At Market Issuance Sales Agreement and potentially amending the loan agreement with Pontifax to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce our debt repayments; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that we will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about our ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, we will not have sufficient cash resources and liquidity to fund our business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms when needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our plans with respect to our liquidity management include, but are not limited to, the following:

- We have up to approximately \$673,000 in active government grant funding still available as of March 31, 2024 to support our associated research programs through May 2026, provided the federal agencies do not elect to terminate the grants for convenience. We plan to submit additional contract and grant applications for further support of our programs with various funding agencies. However, there can be no assurance that we will obtain additional governmental grant funding;
- We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future;
- We will continue to pursue NOL sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program if the program is available;
- We plan to pursue potential partnerships for pipeline programs as well as continue to explore merger and acquisition strategies. However, there can be no assurances that we can consummate such transactions;
- We completed a public offering on April 22, 2024 of 204,694 shares of our Common Stock, pre-funded warrants to purchase 537,500 shares of our Common Stock and common warrants to purchase up to 742,194 shares of our Common Stock at a combined public offering price of \$6.40. The pre-funded warrants have an exercise price of \$0.02. The common warrants have an exercise price of \$6.40 per share, are exercisable immediately and expire five years from the issuance date. The total gross proceeds to us from this offering were approximately \$4.75 million before deducting commissions and other estimated offering expenses of \$0.4 million (\$4.3 net). We plan to use the proceeds for further support of our programs, as well as for working capital. See Note 8 to our quarterly financial statements found elsewhere in this prospectus; and
- We are currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements, we expect our total research and development expenditures for the next 12 months to be approximately \$6.0 million before any contract or grant reimbursements, all of which relates to the Specialized BioTherapeutics business segment. We anticipate contract and grant reimbursements revenue in the next 12 months of approximately \$0.3 million to offset research and development expenses in the Specialized BioTherapeutics business segment.

The table below details our costs for research and development by program and amounts reimbursed for the three months ended March 31, 2024 and 2023:

	2024	2023
Research & Development Expenses		
RiVax® and ThermoVax® Vaccines	\$ 45,839	\$ 30,533
SGX942 (Dusquetide)	19,258	(318)
HyBryte™ (SGX301 or synthetic hypericin)	840,393	822,096
Other	189,550	94,140
Total	\$ 1,095,040	\$ 946,451
Reimbursed under Government Contracts and Grants		
RiVax® and ThermoVax® Vaccines	\$ —	\$ —
CiVax™	—	35,247
SGX943	—	35,429
HyBryte™ (investigator-initiated study)	117,029	155,365
Total	117,029	226,040
Grand Total	\$ 1,212,069	\$ 1,172,491

The table below details our costs for research and development by program and amounts reimbursed for the years ended December 31, 2023 and 2022:

	2023	2022
Research & Development Expenses		
RiVax® and ThermoVax® Vaccines	\$ 133,186	\$ 346,894
SGX942 (Dusquetide)	(28,570)	295,376
CiVax™	—	22,901
HyBryte™ (SGX301 or synthetic hypericin)	2,698,609	6,831,827
Other	509,474	447,091
Total	\$ 3,312,699	\$ 7,944,089
Reimbursed under Government Contracts and Grants		
RiVax® and ThermoVax® Vaccines	\$ —	\$ 22,161
CiVax™	311,495	398,001
SGX943	35,429	98,731
HyBryte™ (investigator-initiated study)	395,124	31,929
Total	742,048	550,822
Grand Total	\$ 4,054,747	\$ 8,494,911

Contractual Obligations

We have licensing fee commitments of approximately \$230,000 as of March 31, 2024 over the next five years for several licensing agreements with partners and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to approximately \$13.2 million, royalties on net sales of covered products ranging from 2% to 3%, sub-license IND milestones on covered products of up to approximately \$200,000, sub-license income royalties on covered products up to 15% and sub-license global net sales royalties on covered products ranging from 1.5% to 2.5%, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

We currently lease office space which serves as our corporate headquarters, and both of our business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended to October 2025. The current rent of \$11,367 per month will be maintained until November 2024 when it will be increased to \$11,625 per month where it will remain until expiration. Our office space is sufficient for our current needs.

In September 2014, we entered into an asset purchase agreement with Hy Biopharma pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, we initially paid \$275,000 in cash and issued 12,328 shares of Common Stock with a fair value based upon our stock price on the date of grant of \$3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to GAAP.

In January 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to increase the number of shares of Common Stock from 334 to 33,334, issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party.

In March 2020, we filed a prospectus supplement covering the offer and sale of up to 130,413 shares of our Common Stock which were issued to Hy Biopharma. We were required to issue the shares to Hy Biopharma as payment following the achievement of a milestone under the asset purchase agreement, specifically, the Phase 3 clinical trial of HyBryte™ being successful in the treatment of CTCL. The number of shares of our common stock issued to Hy Biopharma was calculated using an effective price of \$38.40 per share, based upon a formula set forth in the asset purchase agreement.

Provided the final success-oriented milestone of FDA approval is attained, we will be required to make a payment of up to \$5 million, if and when achieved. The potential future payment will be payable in our Common Stock, not to exceed 19.9% of our outstanding stock. As of March 31, 2024, no other milestone or royalty payments have been paid or accrued.

In December 2020, we entered into a \$20 million convertible debt financing agreement with Pontifax, the healthcare-dedicated venture and debt fund of the Pontifax life science funds. Under the terms of the agreement with Pontifax, we had access to up to \$20 million in convertible debt financing in three tranches, which will mature on June 15, 2025 and had an interest-only period through December 2022 with a rate of 8.47% on borrowed amounts and a 1% rate on amounts available but not borrowed as an unused line of credit fee. After the interest-only period, the outstanding principal was to be repaid in quarterly payments of \$1 million each commencing in the first quarter of 2023. The agreement is secured by a lien covering substantially all of our assets, other than intellectual property.

Upon the closing of this transaction, we borrowed the first tranche of \$10 million. We did not utilize our option to draw the second or third tranche of \$5 million each, which expired on December 15, 2021 and March 15, 2022, respectively.

In April 2023, we entered into an amendment to the convertible debt financing agreement with Pontifax. The amendment required the immediate payment of \$5 million of the outstanding principal balance and any accrued interest, waived any prepayment charge in connection with the repayment of this amount and resulted in an outstanding principal balance of \$3 million. The amendment also provided for a new interest only period from the date of the amendment through June 30, 2024, reduced quarterly principal repayments from \$1 million to \$750,000 and eliminated the minimum cash covenant. Further, the Amendment reduced the conversion price with respect to the remaining principal amount under the agreement to (i) 90% of the closing price of our Common Stock on the day before the delivery of the conversion notice with respect to the first 36,790 shares of our Common Stock issuable upon conversion and to (ii) \$27.20 with respect to all shares of our Common Stock issuable upon conversion in excess of the first 36,790 shares so issued. The remaining terms of the agreement remain in effect without modification.

On January 3, 2024, Pontifax delivered a conversion notice to the Company electing to convert a portion of the remaining principal balance into shares of the Company's Common Stock. Upon conversion, the Company issued 146,199 shares of the Company's Common Stock at \$0.68 per share, reducing the remaining principal

balance by \$99,416. Pontifax may elect to convert the remaining outstanding loan drawn under the first tranche into additional shares of the Company's Common Stock at any time prior to repayment. The Company also has the ability to force the conversion of the loan into shares of its Common Stock, subject to certain conditions.

The amendment to the convertible debt financing agreement with Pontifax resulted in the extinguishment of the original convertible debt for accounting purposes. We elected to account for the amended convertible debt using the fair value option, which requires us to record changes in fair value as a component of other income or expense. The fair value of the convertible debt as of March 31, 2024 was \$2,996,136, which resulted in the recognition of \$165,382 of other income from the change in the fair value of the convertible debt on our accompanying condensed consolidated statements of operations during the three months ended March 31, 2024. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

Interest expense incurred during the three months ended March 31, 2024 and 2023 was \$61,239 and \$187,964, respectively. Interest expense paid during the three months ended March 31, 2024 and 2023 was \$64,047 and \$213,490, respectively.

Contingencies

We follow subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us but which will only be resolved when one or more future events occur or fail to occur. We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment. A liability is only recorded if we determine that it is both probable and reasonably estimable.

BUSINESS

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: Specialized BioTherapeutics and Public Health Solutions.

Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin sodium), a novel photodynamic therapy utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"). With agreement from the European Medicines Agency ("EMA") on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early stage disease, we are targeting to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026. Upon successful completion of the second Phase 3 study, called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2), regulatory approval will be sought to support potential commercialization worldwide.

Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, and our first-in-class IDR technology, dusquetide (SGX942 and SGX945), for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer and aphthous ulcers in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs, targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of the vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority and the Defense Threat Reduction Agency.

An outline of our business strategy follows:

- Following agreement from the EMA on the key design components for the second confirmatory Phase 3 placebo-controlled FLASH2 (Fluorescent Light Activated Synthetic Hypericin 2) clinical trial of HyBryte™ in CTCL and positive primary endpoint results from the first Phase 3 FLASH study, initiate the FLASH2 study, while at the same time, continuing discussions with the U.S. Food and Drug Administration ("FDA") on potential modifications to the development path to adequately address their feedback.
- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.
- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 in the treatment of oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.
- Expanding development of dusquetide under the research name SGX945 into Behçet's Disease with the conduct of a Phase 2a clinical trial, where previous studies with dusquetide

in oral mucositis have validated the biologic activity in aphthous ulcers induced by chemotherapy and radiation.

- Continue development of our heat stabilization platform technology, ThermoVax®, in combination with programs for RiVax® (ricin toxin vaccine), and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses and multivalent combinations), with U.S. government and non-governmental organization funding support.
- Continue to apply for and secure additional government funding for each of our Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.
- Pursue business development opportunities for pipeline programs, as well as explore all strategic alternatives, including but not limited to merger/acquisition strategies.
- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

Specialized BioTherapeutics Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
HyBryte™	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 trial completed; demonstrated statistical significance in primary endpoint in March 2020 (Cycle 1) and demonstrated continued improvement in treatment response with extended treatment in April 2020 (Cycle 2) and October 2020 (Cycle 3); NDA submitted to FDA December 2022; FDA RTF letter received February 2023; second Phase 3 trial based upon EMA-accepted protocol targeted to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026; discussions continue with FDA on modifying the development path to adequately address FDA's preference for a longer duration comparative study over a placebo-controlled trial.
SGX302	Mild-to-Moderate Psoriasis	Positive proof-of-concept demonstrated in a small Phase 1/2 pilot study; Phase 2a protocol and Investigation New Drug ("IND") clearance received from the FDA; Phase 2a study remains ongoing having demonstrated biological effect in Cohort 1 and clinically meaningful benefit in Cohort 2
SGX942†	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial results announced December 2020: the primary endpoint of median duration of severe oral mucositis ("SOM") did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group; analyzed full dataset from Phase 3 study and designing a second Phase 3 clinical trial; continued development contingent upon identification of partnership
SGX945	Aphthous Ulcers in Behçet's Disease	Phase 2a protocol and IND clearance received from the FDA; Phase 2a study to be initiated in the second half of 2024

Public Health Solutions†

Soligenix Product Candidate	Indication	Stage of Development
ThermoVax®	Thermostability of vaccines for Ricin toxin, Ebola, and Marburg viruses	Pre-clinical
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1a, 1b, and 1c trials completed, safety and neutralizing antibodies for protection demonstrated
SGX943	Therapeutic against Emerging Infectious Diseases	Pre-clinical

† Contingent upon continued government contract/grant funding or other funding source.

Specialized BioTherapeutics Overview

Synthetic Hypericin

Synthetic Hypericin is a potent photosensitizer that is topically applied to skin lesions, taken up by cutaneous T-cells and then activated by safe visible light. Hypericin is also found in several species of Hypericum plants, although the active moiety used in HyBryte™ and SGX302 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet ("UV") light. Other light therapies using UVA or UVB light can result in serious adverse effects including secondary skin cancers.

Combined with photoactivation, in clinical trials synthetic hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration as well as a light dose-dependent fashion. These effects appear to result, in part, from the generation of singlet oxygen during photoactivation of hypericin.

Synthetic hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in cells. The use of topical synthetic hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing UV light) is a major advance in photodynamic therapy. In a small published Phase 1/2 proof of concept pilot clinical study using synthetic hypericin twice weekly for six weeks, statistically significant efficacy was demonstrated in patients with CTCL (58.3% response, p=0.04) and psoriasis (80% response, p<0.02). Subsequently, a Phase 3 study in CTCL has further confirmed the biological efficacy of synthetic hypericin (termed HyBryte™ in the context of CTCL).

HyBryte™ – for Treating Cutaneous T-Cell Lymphoma

HyBryte™ is a novel, first-in-class, PDT that utilizes safe visible light for activation. The active ingredient in HyBryte™ is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by visible fluorescent light 16 to 24 hours later.

Based on the positive and previously published Phase 1/2 results, we initiated our Phase 3 clinical study of HyBryte™ for the treatment of CTCL during December 2015 and completed the trial in 2020. This trial, referred to as the "FLASH" (Fluorescent Light Activated Synthetic Hypericin) study, aimed to evaluate the response to HyBryte™ as a skin directed therapy to treat early stage CTCL. We completed the study with approximately 35

CTCL centers across the U.S. participating in this trial. The Phase 3 protocol was a highly powered, double-blind, randomized, placebo-controlled, multicenter trial that enrolled 169 subjects (166 evaluable). The trial consisted of three treatment cycles, each of eight weeks duration. Treatments were administered twice weekly for the first six weeks and treatment response was determined at the end of the eighth week. In the first treatment cycle, approximately 66% of subjects received HyBryte™ and 33% received placebo treatment of their index lesions. In the second cycle, all subjects received HyBryte™ treatment of their index lesions, and in the third cycle, all subjects received HyBryte™ treatment of all of their lesions. The majority of subjects enrolled elected to continue into the third optional, open-label cycle of the study. Subjects were followed for an additional six months after their last evaluation visit. The primary efficacy endpoint was assessed on the percentage of patients in each of the two treatment groups (i.e., HyBryte™ and placebo) achieving a partial or complete response of the treated lesions, defined as a $\geq 50\%$ reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Secondary endpoints for the trial included the duration of responses, the extent of the regression of the tumors, and the safety of the treatment. We continue to work closely with the Cutaneous Lymphoma Foundation, as well as the National Organization for Rare Disorders.

Positive primary endpoint analysis for the Phase 3 study for HyBryte™ was completed in March 2020. The study enrolled 169 patients (166 evaluable) randomized 2:1 to receive either HyBryte™ (116 patients) or placebo (50 patients) and demonstrated a statistically significant treatment response ($p=0.04$) in the CAILS primary endpoint assessment at 8 weeks for Cycle 1. A total of 16% of the patients receiving HyBryte™ achieved at least a 50% reduction in their index lesions compared to only 4% of patients in the placebo group at 8 weeks. HyBryte™ treatment in the first cycle was safe and well tolerated.

Analysis of the second open-label treatment cycle (Cycle 2) was completed in April 2020, showing that continued treatment with HyBryte™ twice weekly for an additional 6 weeks (12 weeks total) increased the positive response rate to 40% ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment). After the subsequent additional 6-week treatment, the response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold. Treatment responses were assessed at Week 8 (after 6 weeks of treatment) and at Week 16 (after 12 weeks of treatment). A positive response was defined as an improvement of at least 50% in the CAILS score for the three index lesions evaluated in both Cycles 1 and 2. The data continued to indicate that HyBryte™ was safe and well tolerated.

Analysis of the optional third open-label treatment cycle (Cycle 3) was completed in October 2020. Cycle 3 was focused on safety and all patients could elect to receive HyBryte™ treatment of all their lesions for an additional 6 weeks or up to 18 weeks in total. Of note, 66% of patients elected to continue with this optional safety cycle of the study. Of the subset of patients that received HyBryte™ throughout all three cycles of treatment (18 weeks), 49% of them demonstrated a treatment response ($p=0.046$ vs. patients completing 12 weeks of HyBryte™ treatment in Cycle 2; $p<0.0001$ vs. patients receiving placebo in Cycle 1). Moreover, in a subset of patients evaluated in this cycle, it was demonstrated that HyBryte™ is not systemically available, consistent with the general safety of this topical product observed to date. At the end of Cycle 3, HyBryte™ continued to be well tolerated despite extended and increased use of the product to treat multiple lesions.

In addition, continued analysis of results from the protocol mandated efficacy cycles (Cycles 1 and 2) of the study revealed that 12 weeks of treatment (Cycle 2) with HyBryte™ is equally effective on both patch (response 37%, $p=0.0009$) and plaque (response 42%, $p<0.0001$) lesions when compared to Cycle 1 placebo lesion responses, further demonstrating the unique benefits of the more deeply penetrating visible light activation of hypericin.

Following the first Phase 3 study of HyBryte™ for the treatment of CTCL, the FDA and the EMA indicated that they would require a second successful Phase 3 trial to support marketing approval. With agreement from the EMA on the key design components, the confirmatory Phase 3 trial will be a randomized, double-blind, placebo-controlled, multicenter study treating approximately 80 subjects with early stage CTCL. It will evaluate the efficacy and safety of HyBryte™ topically applied to CTCL lesions twice weekly for 18 weeks, with each application followed 21 (± 3) hours later by the administration of safe, visible light at a wavelength of 500 to 650

nm. The light will be administered starting at 6 J/cm² twice weekly. This will be increased upwards by 2 J/cm² until: 1) the patient experiences a Grade 1 erythema, 2) the patient reaches the maximum dose of 30 J/cm², or 3) the patient cannot tolerate the treatment time, whichever comes first. All of the patient's lesions that are readily available for exposure to the visible light source will be treated and three to five index lesions of each patient will be prospectively identified and indexed for the modified composite assessment of index lesions severity ("mCAILS") evaluation prior to randomization (baseline). The primary efficacy endpoint will be assessed on the percent of patients in each of the two treatment groups (i.e., HyBryte™ and placebo) achieving a Partial or Complete Response (yes/no) of the treated lesions defined as a ≥ 50% reduction in the total mCAILS score for the three to five index lesions following 18 weeks of treatment compared to the total mCAILS score at baseline. Other secondary measures will assess treatment response (including duration), degree of improvement, time to relapse and safety. Following treatment, all patients will be followed every four weeks for a total of 12 weeks (through Week 30). The Data Monitoring Committee will conduct one (1) interim analysis when approximately 60% of the total subjects have completed the primary endpoint evaluation. The primary efficacy endpoint and the key safety endpoints will be analyzed. A sample size recalculation may be performed after examining the assumptions or the trial halted for either futility, safety concerns, or overwhelming efficacy. The Company, participating clinical investigators, and any personnel involved in trial conduct will remain blinded to study treatment until completion of the trial.

HyBryte™ has received Orphan Drug designation as well as Fast Track designation from the FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for HyBryte™ upon final FDA approval, Orphan Drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a NDA for HyBryte™, and certain tax credits. In addition, Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, we were eligible to submit a NDA for HyBryte™ on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review. HyBryte™ for the treatment of CTCL also was granted Orphan Drug designation from the EMA Committee for Orphan Medical Products and Promising Innovative Medicine ("PIM") designation from the MHRA, as well as Innovation Passport under the Innovative Licensing and Access Pathway ("ILAP") in the UK.

During January 2021, we signed an exclusive Supply, Distribution and Services Agreement with The Daavlin Distributing Co. ("Daavlin"), securing long-term supply and distribution of a commercially ready light device, which is an integral component of the regulatory and commercial strategy for HyBryte™ for the treatment of CTCL. Pursuant to the agreement, Daavlin will exclusively manufacture the proprietary light device for use with HyBryte™ for the treatment of CTCL. Upon approval of HyBryte™ by the FDA, we will promote HyBryte™ and the companion light device, and facilitate the direct purchase of the device from Daavlin. Daavlin will exclusively distribute and sell the HyBryte™ light device to us, physicians and patients.

In April 2021, the FDA conditionally accepted HyBryte™ as the proposed brand name for SGX301 or synthetic hypericin, in the treatment of early stage CTCL. The name HyBryte™ was developed in compliance with the FDA's Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names. The FDA's conditional approval validates HyBryte™ as a proprietary name that is consistent with the FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the HyBryte™ proprietary name is conditioned on FDA approval of the product candidate, SGX301.

In May 2021, HyBryte™ was awarded an "Innovation Passport" for the treatment of early stage CTCL in adults under the UK's ILAP. The decision to award the Innovation Passport to the HyBryte™ program was made by the Innovative Licensing and Access Pathway Steering Group, which is comprised of representatives from MHRA, the National Institute for Health and Care Excellence ("NICE"), and the Scottish Medicines Consortium

("SMC"). ILAP was launched at the start of 2021 to accelerate the development and access to promising medicines, thereby facilitating patient access to new medicines. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with the MHRA, NICE, and SMC. The innovation passport designation is the first step in the ILAP process and triggers the MHRA and its partner agencies to create a target development profile to chart out a roadmap for regulatory and development milestones with the goal of early patient access in the UK. Other benefits of ILAP include a 150-day accelerated assessment, rolling review and a continuous benefit risk assessment.

As a result of discussions with the FDA regarding the HyBryte™ NDA submission and due to disruptions caused by the global COVID-19 pandemic resulting in delays by the commercial active pharmaceutical ingredient ("API") contract manufacturer affecting the timing of availability of the pre-requisite amount of accrued stability data required to file the NDA, we filed the NDA with the FDA in December of 2022. We did not pursue a rolling NDA submission, so that we could provide additional supportive data in the NDA filing.

In June 2021, we received a Paediatric Investigation Plan ("PIP") waiver from the EMA for HyBryte™. As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a PIP outlining their strategies for investigation of the new medicinal products in the pediatric population. In some instances, a waiver negating the need for a PIP for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate, as is the case for HyBryte™ in CTCL which is extremely rare in children.

In September 2021, we were granted orphan drug designation for the active ingredient hypericin for the treatment of T-cell lymphoma, extending the target population beyond CTCL as previously granted by the FDA.

In July 2022, the results of our successful Phase 3 FLASH study evaluating HyBryte™ for the treatment of CTCL were published in the Journal of the American Medical Association (JAMA) Dermatology.

In July 2022, we received agreement from the FDA on an initial pediatric study plan ("iPSP") for HyBryte™ for the treatment of CTCL. The agreed iPSP stipulates that we intend to request a full waiver of pediatric studies upon submission of the NDA. Agreement with FDA on an iPSP is one of the regulatory requirements that must be met prior to submitting a NDA.

In September 2022, the FDA awarded an Orphan Products Development grant to support the evaluation of HyBryte™ for expanded treatment in patients with early stage CTCL. The grant, totaling \$2.6 million over four years, was awarded to a prestigious academic institution that was a leading enroller in the published positive Phase 3 FLASH study in the treatment of early stage CTCL.

In December 2022, we submitted the HyBryte™ NDA for the treatment of CTCL with the FDA.

In February 2023, we received a RTF letter from the FDA for the HyBryte™ NDA. Upon preliminary review, the FDA determined that the NDA was not sufficiently complete to permit substantive review.

In April 2023, the United States Adopted Names ("USAN") Council approved the use of the nonproprietary name of "hypericin sodium" for the novel active ingredient in both HyBryte™ (research name SGX301) for the treatment of CTCL and SGX302 for the treatment of mild-to-moderate psoriasis.

In April 2023, we had a Type A meeting with the FDA to clarify and respond to the issues identified in the RTF letter received from the FDA and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards marketing approval and U.S. commercialization. In order to accept an NDA filing for HyBryte™, the FDA is requiring positive results from a second, Phase 3 pivotal study in addition to the Phase 3, randomized, double-blind, placebo-controlled FLASH study previously conducted in this orphan indication. Based on this feedback, we have decided to collaboratively engage in discussions with the FDA in order to define the protocol and evaluate the feasibility of conducting the additional clinical trial.

In May 2023, we were granted a follow-on Type A meeting with the FDA to initiate formal discussions regarding the protocol design of a second, Phase 3 pivotal study evaluating HyBryte™ in the treatment of CTCL in support of potential FDA marketing approval. While discussions have been collaborative, the FDA has expressed a preference for a longer duration comparative study over a placebo-controlled trial. Given the shorter time to potential commercial revenue and the similar trial design to the first FLASH study afforded by the EMA accepted protocol, we determined to initiate the FLASH2 study in support of worldwide potential approval. At the same time, we will continue discussions with the FDA on modifying the development path to adequately address their feedback.

In August 2023, patient enrollment was opened for the investigator-initiated study ("IIS"). IIS is supported by an Orphan Products Development grant of \$2.6 million over four years awarded by the FDA to Ellen Kim, MD, Director, Penn Cutaneous Lymphoma Program, Vice Chair of Clinical Operations, Dermatology Department, and Professor of Dermatology at the Hospital of the University of Pennsylvania who was a leading enroller in the published positive Phase 3 FLASH study in the treatment of early stage CTCL. The IIS will evaluate the expanded treatment, including up to 12 months of treatment, with HyBryte™ in patients with early stage CTCL.

In March 2024, we received agreement from the EMA on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early stage disease. This confirmatory 18-week study is expected to enroll approximately 80 patients in the US and Europe and is targeted to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026.

In June 2024, we announced positive clinical results from a comparability study evaluating HyBryte™ versus Valchlor® (mechlorethamine gel) in the treatment of early stage CTCL. The open-label study enrolled 10 patients (5 patients per group) with treatment success defined as a ≥50% improvement in a patient's cumulative mCAILS score after 12 weeks of topical treatment compared to Baseline. The study demonstrated that HyBryte™ treatment resulted in 60% of patients achieving a 50% or better improvement in their mCAILS score versus 20% of Valchlor® patients. When comparing the tolerance of the topical therapies in this trial, it is notable that all patients tolerated HyBryte™ well and had no adverse events "Related" to the therapy. In contrast, 60% of the Valchlor® treated patients had at least one adverse event "Related" to the therapy. These adverse events in the Valchlor® group included rashes, application site sensitivity, allergic contact dermatitis, and dermatitis, with one patient requiring steroid treatment, one requiring temporary interruption of Valchlor® treatment, and one requiring permanent discontinuation of Valchlor®. No such instances were reported in the HyBryte™ group.

In July 2024, we announced an interim update on the open-label, investigator-initiated study (IIS) evaluating extended HyBryte™ treatment for up to 12 months in patients with early stage CTCL. To date, the trial sponsored by Dr. Ellen Kim, has enrolled and treated six patients with HyBryte™ over a time period ranging up to 44 weeks. Patients have responded positively to HyBryte™ therapy with 75% (3 of the 4 subjects who have completed at least 12 weeks of therapy) already achieving "Treatment Success", as predefined in the study's protocol as ≥50% improvement in their cumulative mCAILS score compared to Baseline. Of the three Treatment Successes, two were achieved within the first 12 weeks of treatment and the third within 18 weeks. Of the remaining three patients, two have only recently started HyBryte™ therapy and have not yet reached their first efficacy evaluation visit (i.e., at Week 6) and the other had a substantial improvement documented at the Week 18 visit, but has not yet achieved the success threshold. In addition, HyBryte™ appears to be safe and well tolerated in all patients, with no treatment-related adverse events reported to date.

We estimate the potential worldwide market for HyBryte™ is in excess of \$250 million for the treatment of CTCL. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Cutaneous T-Cell Lymphoma

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses (expected five-year survival rate of 24%), than those with MF (expected five-year survival rate of 88%).

CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no FDA-approved drug for front-line treatment of early stage CTCL. Treatment of early stage disease generally involves skin-directed therapies. One of the most common unapproved therapies used for early stage disease is oral 5 or 8-methoxypsoralen ("Psoralen") given with ultraviolet A ("UVA") light, referred to as PUVA, which is approved for dermatological conditions such as disabling psoriasis not adequately responsive to other forms of therapy, idiopathic vitiligo and skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. Psoralen is a mutagenic chemical that interferes with DNA causing mutations and other malignancies. Moreover, UVA is a carcinogenic light source that when combined with the Psoralen, results in serious adverse effects including secondary skin cancers; therefore, the FDA requires a Black Box warning for PUVA.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the more than 1.7 million individuals living with the disease in the United States and Europe (European Union and United Kingdom). It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL that it affects approximately 31,000 individuals in the U.S. (based on SEER data, with approximately 3,200 new cases seen annually) and approximately 38,000 individuals in Europe (based on ECIS prevalence estimates, with approximately 3,800 new cases annually).

SGX302 – for Treating Mild-to-Moderate Psoriasis

SGX302 (synthetic hypericin) is a potent photosensitizer that is topically applied to skin lesions and taken up by cutaneous T-cells. With subsequent activation by safe, visible light, T-cell apoptosis is induced, addressing the dysregulated T-cells found in psoriasis lesions. Other PDTs have shown efficacy in psoriasis with a similar apoptotic mechanism, albeit using UV light associated with more severe potential long-term toxicities. The use of visible light in the red-yellow spectrum has the advantage of deeper penetration into the skin (much more than UV light) potentially treating deeper skin disease and thicker plaques and lesions, similar to what was observed in the positive Phase 3 FLASH study in CTCL. Further, this treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with both the frequently used DNA-damaging drugs and other phototherapies that are dependent on UVA or UVB exposure. The use of SGX302 coupled with safe, visible light also avoids the risk of serious infections and cancer associated with the systemic immunosuppressive treatments used in psoriasis.

In September 2021, following the validation of synthetic hypericin's biologic activity in the positive Phase 3 FLASH study in CTCL, as well as positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients, we decided to expand this novel therapy into a Phase 2a clinical trial in mild-to-moderate psoriasis.

In June 2022, we received FDA IND clearance for our Phase 2a clinical trial (protocol number HPN-PSR-01) titled, "Phase 2 Study Evaluating SGX302 in the Treatment of Mild-to-Moderate Psoriasis." In December 2022, we initiated patient enrollment for the Phase 2a study (protocol number HPN-PSR-01) evaluating SGX302 in the treatment of mild-to-moderate psoriasis. The Phase 2a clinical trial (protocol number HPN-PSR-01) will target enrollment of up to 42 patients ages 18 years or older with mild to moderate, stable psoriasis covering 2 to 30% of the body. In both Parts A and B, all patients will apply the study drug twice per week and activate the drug with visible light 24 ± 6 hours later using the supplied visible light devices and according to the manufacturer's instructions. Patients will undergo treatments for a total of 18 weeks and, on completion, will be followed for a four-week follow-up period in which patients will not receive other psoriasis treatments. In Part A, five to ten patients will be assigned open-label SGX302 (0.25% hypericin) at the time of enrollment. Once the tolerability and response to SGX302 has been established, Part B of the protocol will commence. In Part B, patients will be randomized to double-blind treatment groups at a ratio 1:1 of active drug to placebo ointment.

Active dermatologic assessment of treated lesions for adverse events will be performed immediately before and during light treatments. Patients will be assessed for overall disease status through four weeks of follow-up. Efficacy endpoints will include the extent of lesion clearance and patient reported quality of life indices. Routine safety data also will be collected.

In October 2022, we announced the formation of a Medical Advisory Board to provide medical/clinical strategic guidance to advance the Phase 2a clinical development of SGX302 for the treatment of mild-to-moderate psoriasis.

In July 2023, we expanded the Phase 2a trial of SGX302 after demonstration of biological effect in the initial five subjects (Cohort 1). The study is expected to enroll at least an additional ten subjects, exploring the use of SGX302 in the standard of care psoriasis setting, prior to undertaking the larger phase of the study.

In January 2024, positive preliminary results of clinical success were demonstrated in the Cohort 2 subjects enrolled in the ongoing Phase 2a study. In the four evaluable patients from Cohort 2 (one patient withdrew early in the treatment course for personal reasons unrelated to the study), two reached a disease status of "Almost Clear" represented by an Investigator Global Assessment score of 1, which is considered the standard clinical measure for treatment success in psoriasis. In addition, the Psoriasis Activity and Severity Index score, another well-characterized measure of treatment success, for patients in Cohort 2 had a mean drop of approximately 50% over the 18-week treatment. SGX302 therapy was well tolerated by all patients with no drug related adverse events identified.

We estimate the potential worldwide market for SGX302 is in excess of \$1 billion for the treatment of mild-to-moderate psoriasis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Psoriasis

Psoriasis is a chronic, non-communicable, itchy and often painful inflammatory skin condition for which there is no cure. Psoriasis has a significantly detrimental impact on patients' quality of life, and is associated with cardiovascular, arthritic, and metabolic diseases, as well as psychological conditions such as anxiety, depression and suicide. Many factors contribute to development of psoriasis including both genetic and environmental factors (e.g., skin trauma, infections, and medications). The lesions develop because of rapidly proliferating skin cells, driven by autoimmune T-cell mediated inflammation. Of the various types of psoriasis, plaque psoriasis is the most common and is characterized by dry, red raised plaques that are covered by silvery-white scales occurring most commonly on the elbows, knees, scalp, and lower back. Approximately 80% of patients have mild-to-moderate disease. Mild psoriasis is generally characterized by the involvement of less than 3% of the body surface area ("BSA"), while moderate psoriasis will typically involve 3-10% BSA and severe psoriasis greater than 10% BSA. Between 20% and 30% of individuals with psoriasis will go on to develop

chronic, inflammatory arthritis (psoriatic arthritis) that can lead to joint deformations and disability. Studies have also associated psoriasis, and particularly severe psoriasis, with an increased relative risk of lymphoma, particularly CTCL. Although psoriasis can occur at any age, most patients present with the condition before age 35.

Treatment of psoriasis is based on its severity at the time of presentation with the goal of controlling symptoms. It varies from topical options including PDT to reduce pain and itching, and potentially reduce the inflammation driving plaque formation, to systemic treatments for more severe disease. Most common systemic treatments and even current topical photo/photodynamic therapy such as UV A and B, carry a risk of increased skin cancer.

Psoriasis is the most common immune-mediated inflammatory skin disease. According to the World Health Organization ("WHO") Global Report on Psoriasis 2016, the prevalence of psoriasis is between 1.5% and 5% in most developed countries, with some suggestions of incidence increasing with time. It is estimated, based upon review of historic published studies and reports and an interpolation of data that psoriasis affects 3% of the U.S. population or more than 7.5 million people. Current estimates have as many as 60-125 million people worldwide living with the condition. The global psoriasis treatment market was valued at approximately \$15 billion in 2020 and is projected to reach as much as \$40 billion by 2027.

Dusquetide

Dusquetide (research name: SGX94) is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. Dusquetide is based on a new class of short, synthetic peptides known as IDRs. It has a novel mechanism of action in that it modulates the body's reaction to both injury and infection and is both simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs represent a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs may be active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy. Additionally, due to selective binding to p62, dusquetide may have potential anti-tumor action.

Dusquetide has demonstrated efficacy in numerous animal disease models including mucositis, oncology, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. Dusquetide was shown to have a good safety profile and be well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. We believe that market opportunities for dusquetide include, but are not limited to, oral and gastrointestinal mucositis, oncology (e.g., breast cancer), acute Gram-positive bacterial infections (e.g., methicillin resistant *Staphylococcus aureus* ("MRSA")), acute Gram-negative infections (e.g., *acinetobacter*, *meloidosis*), and acute radiation syndrome.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA. In addition, dusquetide has been granted PIM designation in the UK by the MHRA for the treatment of SOM in head and neck cancer patients receiving chemoradiation therapy.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in December of 2013. We completed enrollment in this trial and released positive results in December 2015. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of SOM by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. A less severe occurrence of oral mucositis, ulcerative oral mucositis (defined as oral mucositis with a WHO score ≥ 2 corresponding to the occurrence of overt ulceration in the mouth), was also monitored during the study. In the patients receiving the most aggressive chemoradiation therapy, the median duration of oral mucositis was found to decrease from 65 days in the placebo treated patients to 51 days in the patients treated with SGX942 1.5 mg/kg ($p=0.099$).

In addition to identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of "complete response" of tumor at the one month follow-up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models. Data from this Phase 2 trial are published in the Journal of Biotechnology.

SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. The long-term (12 month) follow-up data was consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group). The long-term follow-up results from the Phase 2 study are published in Biotechnology Reports.

In September 2016, we and SciClone Pharmaceuticals, Inc. ("SciClone") entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in defined territories. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

Based on the positive and previously published Phase 2 results (Study IDR-OM-01), in July 2017, we initiated a Phase 3 clinical trial referred to as the "DOM-INNATE" (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) study. Approximately 50 U.S. and European oncology centers participated in this trial. The Phase 3 protocol (Study IDR-OM-02) was a highly powered, double-blind, randomized, placebo-controlled, multinational trial that sought to enroll approximately 260 subjects with squamous cell carcinoma of the oral cavity and oropharynx who were scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m² every third week. Subjects were randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of chemoradiation therapy ("CRT"). The primary endpoint for the study was the median duration of SOM, which was assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis is evaluated using the WHO Grading system. SOM is defined as a WHO Grade of ≥ 3 . Subjects are followed for an additional 12 months after the completion of treatment.

In April 2019, the Paediatric Committee of the EMA approved our PIP for SGX942, a prerequisite for filing a Marketing Authorization Application ("MAA") for any new medicinal product in Europe. The EMA also agreed that we may defer conducting the PIP until successful completion of our pivotal Phase 3 clinical trial of SGX942, which allowed us to file the adult indication MAA prior to completion of the PIP.

In June 2020, the pivotal Phase 3 DOM-INNATE study (Study IDR-OM-02) completed enrollment of 268 subjects. In December 2020, the results of our Phase 3 clinical trial for SGX942 showed that the primary endpoint of median duration of SOM did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group. Despite this clinically meaningful improvement, the variability in the distribution of the data yielded a p-value that was not statistically significant. Other secondary endpoints supported the biological activity of dusquetide, including a statistically significant 50% reduction in the median duration of SOM in the per-protocol population, which decreased from 18 days in the placebo group to 9 days in the SGX942 treatment group ($p = 0.049$), consistent with the findings in the Phase 2 trial (Study IDR-OM-01). Similarly, incidence of SOM also followed this biological trend as seen in the Phase 2 study, decreasing by 16% in the SGX942 treatment group relative to the placebo group in the per-protocol population. The per-protocol population was defined as the population receiving a minimum of 55 Gy radiation and at least 10 doses of study drug (placebo or SGX942) throughout the intended treatment period, with no major protocol deviations (e.g. breaks in study drug administration longer than 8 days between successive doses).

Following analysis of the full dataset, including the 12-month long-term follow-up safety data in late 2021, we held a meeting with the MHRA to review the study results and to obtain further clarity on the future of the oral mucositis development program. The meeting was informative with the outcome being that based on the SGX942 biologic activity observed and the consistency in response between the Phase 2 and Phase 3 trials, the Phase 3 DOM-INNATE study could serve as the first of two Phase 3 studies required to support potential marketing authorization, assuming the second Phase 3 clinical trial achieves the required level of statistical significance in its primary endpoint. With the benefit of a robust preclinical and clinical data package for SGX942, we now will analyze the data to design a second Phase 3 study and will look to identify a potential partner(s) to continue this development program.

In January 2022, dusquetide proved effective at reducing tumor size in nonclinical xenograft models. Recent studies, recapitulating results from previously published studies, have confirmed the efficacy of dusquetide as a stand-alone and combination anti-tumor therapy, with radiation, chemotherapy and targeted therapy, in the context of the MCF-7 breast cancer cell line. Of note, these results are consistent with a potential direct anti-tumor effect identified with SGX942 and is another important consideration in the oral mucositis treatment space.

In June 2022, an article was published describing the binding of our IDR, dusquetide, to the p62 protein. Dusquetide binds to p62 or SQSTM-1, a scaffold protein implicated in a number of intracellular signaling networks implicated in tumor cell survival, including autophagy. This publication elaborates on the direct interaction of dusquetide with p62, as well as some of the direct downstream consequences of that interaction, consistent with its observed anti-infective, anti-tumor and anti-inflammatory activities. This information advances the understanding of dusquetide's novel mechanism of action and supports the development of analogs related to dusquetide.

We estimate the potential worldwide market for SGX942 is in excess of \$500 million for the treatment of oral mucositis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral

nutrition and narcotic analgesia. The gastrointestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

SGX945 – for Treating Aphthous Ulcers in Behçet’s Disease

SGX945 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of aphthous Ulcers in Behçet’s Disease. Behçet’s Disease is an orphan disease and an area of unmet medical need.

In November 2023, the FDA cleared the IND application for a Phase 2a clinical trial entitled, “ *Pilot Study of SGX945 (Dusquetide) in the Treatment of Aphthous Ulcers in Behçet’s Disease.*” The study is designed to evaluate the safety and potential efficacy of SGX945 (dusquetide) in the resolution of aphthous flares in Behçet’s Disease and is expected to begin patient enrollment in the second half of 2024.

In January 2024, SGX945 received Fast Track designation for the treatment of oral lesions of Behçet’s Disease from the FDA.

In February 2024, we announced the formation of a Medical Advisory Board to provide medical/clinical strategic guidance to advance the clinical development of SGX945 for the treatment of Behçet’s Disease.

We estimate the potential worldwide market for SGX945 is in excess of \$200 million for the treatment of aphthous ulcers in Behçet’s Disease. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Behçet’s Disease

Behçet’s Disease (“BD”) is commonly known as an inflammatory disorder of the blood vessels (vasculitis). Often first diagnosed in young adults, its effects and severity will wax and wane over time. Major signs and symptoms usually include mouth sores (approximately 95% of patients), skin rashes and lesions (approximately 50% of patients), genital sores (approximately 50% of patients), leg ulcers (approximately 40% of patients) and eye inflammation (approximately 15% of patients). It is a painful disease, directly impacting the patient’s quality of life and ability to productively engage in life activities, including work.

BD is thought to be an auto-immune disease with both genetic and environmental factors. It is most common along the “silk road” in the Middle East and East Asia, including Turkey, Iran, Japan and China. There are approximately 18,000 known cases of BD in the U.S. and 80,000 in Europe. There are as many as 1,000,000 people worldwide living with BD.

There is no cure for BD, rather treatments are prescribed to manage symptoms. Treatments may include both maintenance therapies and those specifically addressing mucocutaneous flares (e.g., mouth ulcers, genital

ulcers and leg ulcers). Corticosteroids are generally applied topically to sores and as eyedrops and may also be given systemically to reduce inflammation. Although used frequently, they have limited efficacy over the long-term and have significant side effects that become more concerning with more chronic use. Genital ulcers are often associated with significant genital scarring while leg ulcers can result in a post-thrombotic syndrome. Other treatments for BD flares involve suppressing the immune system with drugs (e.g., cyclosporine or cyclophosphamide). These drugs come with a higher risk of infection, liver and kidney problems, low blood counts and high blood pressure. Finally, anti-inflammatory drugs are also used, including anti-TNF medications. The only approved drug in BD is apremilast, which is used as a maintenance therapy to prevent formation of oral ulcers. Unfortunately, apremilast is associated with both high cost and side effects including diarrhea, nausea, upper respiratory tract infection and headache.

Public Health Solutions Overview

ThermoVax® – Thermostability Platform Technology

ThermoVax® is a novel method for thermostabilizing vaccines with a variety of adjuvants, resulting in a single vial which can be reconstituted with water for injection immediately prior to use. One of the adjuvants utilized in ThermoVax® is aluminum salts (known colloquially as “Alum”). Alum is the most widely employed adjuvant technology in the vaccine industry.

The value of ThermoVax® lies in its potential ability to eliminate the need for cold chain production, transportation, and storage for Alum-adjuvanted vaccines. This would relieve the high costs of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from WHO and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that many vaccines need to be maintained either between 2 and 8 degrees Celsius (“C”), frozen below -20 degrees C, or frozen below -60 degrees C, and even brief excursions from these temperature ranges usually necessitate the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines for ricin exposure in emergency settings.

ThermoVax® development, specifically in the context of an Alum adjuvant, was supported pursuant to our \$9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax®) and anthrax vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our Alum-adjuvanted ricin toxin vaccine, RiVax® and our Alum-adjuvanted anthrax vaccine. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax® was kept at 40 degrees C (104 degrees Fahrenheit (“F”)) for up to one year, all of the animals vaccinated with the lyophilized RiVax® vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax® vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When the anthrax vaccine was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we also have demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists.

We also entered into a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (“JABSOM”), University of Hawai‘i at Manoa (“UH Manoa”) and Hawaii Biotech, Inc. (“HBI”) to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates (“NHP”). The most advanced Ebola vaccines involve the use of vesicular stomatitis virus and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and

storage requirements. Dr. Lehrer's vaccine candidate is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax® may allow for a product that can avoid the need for cold chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world. This agreement has expired in accordance with its terms.

In December 2010, we executed a worldwide exclusive license agreement with the University of Colorado ("UC") for certain patents relating to ThermoVax® in all fields of use. In April 2018, the UC delivered a notice of termination of our license agreement based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC, we and the UC agreed to extend the termination date to October 31, 2018 in order to allow us time to agree upon a potential agreement that would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology in our field of use.

During September 2017, we were awarded funding of approximately \$700,000 over five years under a NIAID Research Project (R01) grant awarded to UH Manoa for the development of a trivalent thermostabilized filovirus vaccine (including protection against Zaire ebolavirus, Sudan ebolavirus and Marburg Marburgvirus). Previous collaborations demonstrated the feasibility of developing a heat stable subunit Ebola vaccine. Under the terms of the subaward, we will continue to support vaccine formulation development with our proprietary vaccine thermostabilization technology, ThermoVax®. Ultimately, the objective is to produce a thermostable trivalent filovirus vaccine for protection against Ebola and related diseases, allowing worldwide distribution without the need for cold storage. Based on current U.S. government needs, efforts have been expanded to focus on a monovalent or bivalent vaccine to specifically address Marburg marburgvirus.

In October 2018, in a series of related transactions, (a) we and the UC agreed to terminate the original license agreement, (b) the UC and VitriVax, Inc. ("VitriVax") executed a worldwide exclusive license agreement for the heat stabilization technology for all fields of use, and (c) we and VitriVax executed a worldwide exclusive sublicense agreement, which was amended and restated in October 2020, for the heat stabilization technology for use in the fields of ricin and Ebola vaccines. We paid a \$100,000 sublicense fee on the effective date of the sublicense agreement. Under the amended sublicense agreement to maintain the sublicense we are obliged to pay a minimum annual royalty of \$20,000 until first commercial sale of a sublicensed product, upon which point, we shall pay an earned royalty of 2% of net sales subject to a minimum royalty of \$50,000 each year. We are also required to pay royalty on any sub-sublicense income based on a declining percentage of all sub-sublicense income calculated within the contractual period until reaching a minimum of 15% after two years. In addition, we are required to pay VitriVax milestone fees of: (a) \$25,000 upon initiation of a Phase 2 clinical trial of the sublicensed product, (b) \$100,000 upon initiation of a Phase 3 clinical trial of the sublicensed product, (c) \$100,000 upon regulatory approval of a sublicensed product, and (d) \$1 million upon achieving \$10 million in aggregate net sales of a sublicensed product in the U.S. or equivalent. To date none of these milestones have been met.

In March 2020, we entered into a research collaboration with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UH Manoa to further expand the filovirus collaboration to investigation of potential coronavirus vaccines, including for SARS-CoV-2 (causing COVID-19). This research collaboration will utilize the technology platform developed in the search for filovirus vaccines and will use well-defined surface glycoprotein(s) from one or more coronaviruses, which are expected to be protective for COVID-19.

During April 2020, we obtained an exclusive worldwide license for CoVaccine HT™, a novel vaccine adjuvant, from SERB Pharmaceuticals (formerly BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation) ("SERB"), for the fields of coronavirus infection (including SARS-CoV-2, the cause of COVID-19), and pandemic flu. CoVaccine HT™ is a novel adjuvant, which has been shown to enhance both cell-mediated and antibody-mediated immunity. We and our collaborators, including UH Manoa and Dr. Axel Lehrer, have successfully demonstrated the utility of CoVaccine HT™ in the development of our heat stable filovirus vaccine

program, with vaccine candidates against Ebola and Marburg virus disease. Given this previous success, CoVaccine HT™ will potentially be an important component of our vaccine technology platform currently being assessed for use against coronaviruses including SARS-CoV-2, the cause of COVID-19. The license agreement was executed between us and SERB, which owns the CoVaccine HT™ intellectual property.

In September 2020, the Journal of Pharmaceutical Sciences published a scientific article detailing the thermostabilization of the filovirus GP proteins and key assays describing their stability.

During October 2020, Frontiers in Immunology published a scientific article describing CiVax™, a prototype COVID-19 vaccine, using the novel CoVaccine HT™ adjuvant and demonstrating significant immunogenicity, including strong total and neutralizing antibody responses, with a balanced Th1 response, as well as enhancement of cell mediated immunity. These are all considered to be critical attributes of a potential COVID-19 vaccine.

In December 2020, NIAID awarded us a Direct to Phase II Small Business Innovation Research ("SBIR") grant of approximately \$1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and Ebola Virus Disease ("EVD") vaccine candidates in conjunction with the CoVaccine HT™ adjuvant. This award also is supporting immune characterization of this novel, emulsified adjuvant that has unique potency and compatibility with lyophilization strategies to enable thermostabilization of subunit vaccines.

During August 2021, positive data demonstrated the efficacy of multiple filovirus vaccine candidates in NHP, including thermostabilized multivalent vaccines in a single vial platform presentation. Collaborators at UH Manoa describe the potent efficacy of vaccine candidates protecting against three life-threatening filoviruses, Zaire ebolavirus, Sudan ebolavirus and Marburg Marburgvirus in an article titled "Recombinant Protein Filovirus Vaccines Protect Cynomolgus Macaques from Ebola, Sudan, and Marburg Viruses", published in Frontiers in Immunology. These vaccine candidates contain highly purified protein antigens combined with the novel CoVaccine HT™ adjuvant, in both monovalent (single antigen) and bivalent (two antigen) formulations. Most recently, efforts to formulate all three antigens and adjuvant into a thermostable single-vial vaccine platform has also been shown to protect 75% of vaccinated NHPs against subsequent Sudan ebolavirus challenge, with further development to test efficacy against other filovirus infections ongoing.

During August 2021, Vaccine published a scientific article describing the formulation of single-vial platform presentations of monovalent (single antigen), bivalent (two antigens) and trivalent (three antigens) combinations of filovirus vaccine candidates.

During September 2021, an accelerated preprint was posted on bioRxiv of pre-clinical immunogenicity studies for CiVax™ (heat stable COVID-19 vaccine program) demonstrating durable broad-spectrum neutralizing antibody responses, including against the Beta, Gamma and Delta variants of concern. The scientific article was subsequently published on March 9, 2022 in ACS Infectious Diseases. The work is part of an ongoing collaboration with Axel Lehrer, PhD, Associate Professor at the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UH Manoa. Development continues under a non-dilutive \$1.5M grant from the NIAID awarded to us in December 2020.

In December 2021, 100% protection of NHPs against lethal Sudan ebolavirus challenge was achieved using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with water immediately prior to use. This milestone is part of an ongoing collaboration with UH Manoa and further demonstrates the broad applicability of the vaccine platform, and its potential role in the U.S. government's initiative for pandemic preparedness.

In May 2022, the U.S. Patent and Trademark Office issued a Notice of Allowance for the patent application titled "Composition and Methods of Manufacturing Trivalent Filovirus Vaccines." The allowed claims are directed to unique, proprietary composition and methods directed to combinations of glycoprotein antigens with nano-emulsion adjuvants comprising sucrose fatty acid esters prior to lyophilization. The described vaccine

platform has previously been successfully applied to filovirus vaccines (as mono-, bi- and tri-valent candidates for Zaire ebolavirus, Sudan ebolavirus and Marburg marburgvirus) as well as SARS-CoV-2 vaccine. No currently licensed lyophilized vaccine that contains an adjuvant is presented in a single vial format and there are few reports of successfully using nano-emulsions in lyophilized formulations. Previous work has demonstrated the use of a single vial platform to co-lyophilize antigen(s) and a nano-emulsion adjuvant, CoVaccine HT™, maintaining key adjuvant stability characteristics including particle size and colloidal stability, as well as maintaining immunogenicity. This most recent milestone confirms that, in the context of lethal challenge with Sudan ebolavirus, complete protection is maintained with the thermostabilized formulation.

In June 2022, 100% protection of NHPs against lethal Marburg marburgvirus challenge was achieved using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with sterile water immediately prior to use. This important milestone is part of an ongoing collaboration with UH Manoa, demonstrating the successful presentation of one or more antigen(s) within the same formulation while maintaining full potency and thermostability. It further demonstrates the broad applicability of the heat stable vaccine platform, and its potential role in the U.S. government's initiative for pandemic preparedness.

In September 2023, positive data demonstrated two-year stability of thermostabilized bivalent and trivalent filovirus vaccine candidates at temperatures of 40 degrees C (104 degrees F) when formulated in a single vial, needing reconstitution only with sterile water immediately prior to use. This important milestone is part of an ongoing collaboration with UH Manoa, demonstrating the successful presentation of one or more antigen(s) within the same formulation while maintaining full potency and thermostability. It further demonstrates the broad applicability of the heat stable vaccine platform, and its potential role in the U.S. government's initiative for pandemic preparedness.

In January 2024, Vaccine published the preclinical efficacy results of our novel, single-vial, thermostabilized bivalent filovirus vaccine providing 100% protection against both *Sudan ebolavirus* (SUDV) and *Marburg marburgvirus* (MARV) infections. The manuscript was entitled "*Thermostable bivalent filovirus vaccine protects against severe and lethal Sudan ebolavirus and marburgvirus infection*".

In April 2024, we received orphan drug designation for the active ingredient in SuVax™, the subunit protein vaccine of recombinantly expressed SUDV glycoprotein, for the prevention and post-exposure prophylaxis against SUDV infection.

In April 2024, we received orphan drug designation for the active ingredient in MarVax™, the subunit protein vaccine of recombinantly expressed MARV glycoprotein, for the prevention and post-exposure prophylaxis against MARV infection.

In April 2024, we received notice of intent to grant additional patents based on our patent application titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines" in the United Kingdom and South Africa, with other international jurisdictions pending.

RiVax® – for Protection Against Ricin Toxin Exposure

RiVax® is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved, would be the first ricin vaccine. The immunogen in RiVax® induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated ricin A chain subunit that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax® has demonstrated statistically significant ($p < 0.0001$) preclinical survival results, providing 100% protection against acute lethality in an aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA 112:3782-3787), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax® established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of

conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial that was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center ("UTSW") evaluated a more potent formulation of RiVax® that contained an Alum adjuvant. The results of the Phase 1b study indicated that Alum-adjuvanted RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. The outcomes of this second study were published in the Clinical and Vaccine Immunology.

We have adapted the original manufacturing process for the immunogen contained in RiVax® for thermostability and large scale manufacturing and recent studies have confirmed that the thermostabilized RiVax® formulation enhances the stability of the RiVax® antigen, enabling storage for at least 1 year at temperatures up to 40 degrees C (104 degrees F). The program will pursue approval via the FDA "Animal Rule" since it is not possible to test the efficacy of the vaccine in a clinical study which would expose humans to ricin. Uniform, easily measured and species-neutral immune correlates of protection that can be measured in humans and animals, and are indicative of animal survival to subsequent ricin challenge, are central to the application of the "Animal Rule." Recent work has identified such potential correlates of immune protection in animals and work to qualify and validate these approaches is continuing, with the goal of utilizing these assays in a planned Phase 1/2 clinical trial with the thermostable RiVax® formulation. During September 2018, we published an extended stability study of RiVax®, showing up to 100% protection in mice after 12 months storage at 40 degrees C (104 degrees F) as well as identification of a potential in vitro stability indicating assay, critical to adequately confirming the long-term shelf life of the vaccine. We have entered into a collaboration with IDT Biologika GmbH ("IDT") to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. We also initiated a development agreement with Emergent BioSolutions, Inc. ("EBS") to implement a commercially viable, scalable production technology for the RiVax® drug substance protein antigen.

The development of RiVax® has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to us and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately \$25 million in grant funding from the NIH for the development of RiVax®. In September 2014, we entered into a contract with the NIH for the development of RiVax® pursuant to which we were awarded an additional \$21.2 million of funding in the aggregate. The development agreements with EBS and IDT were specifically funded under this NIH contract.

In 2017, NIAID exercised options to fund additional animal efficacy studies and good manufacturing practices compliant RiVax® bulk drug substance and finished drug product manufacturing, which is required for the conduct of future preclinical and clinical safety and efficacy studies. The exercised options provide us with approximately \$4.5 million in additional non-dilutive funding, bringing the total amount awarded to date under this contract to \$21.2 million, which expired in February 2021. The total award of up to \$21.2 million supported the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax® with the FDA. In addition to this funding for the development of RiVax®, biomarkers for RiVax® testing have been successfully identified, facilitating potential approval under the FDA Animal Rule.

During December 2019, we initiated a third Phase 1 double-blind, placebo-controlled, randomized study in eight healthy adult volunteer subjects designed to evaluate the safety and immunogenicity of RiVax® utilizing ThermoVax®. During January 2020, we suspended the study after Emergent Manufacturing Operations Baltimore LLC ("EMOB"), the manufacturer of the drug substance, notified us that, after releasing the final drug product to us, EMOB identified that the active drug substance tested outside the established specification parameters. Two subjects had received doses as part of the study before the manufacturer provided this notice. Those two subjects were monitored with no safety issues noted and data was captured in accordance with the study protocol. They did not receive further doses of study drug.

During April 2020, we received notification from NIAID that they would not be exercising the final contract option to support the conduct of a Phase 1/2 clinical study in healthy volunteers. As a result, the total contract award will not exceed \$21.2 million. This contract expired in February 2021.

In November 2021, an article was published on pre-clinical immunogenicity studies for RiVax[®] demonstrating enduring protection for at least 12 months post-vaccination. These results, coupled with the previous demonstration of efficacy in mice and NHPs as well as long-term thermostability (at least 1 year at 40 degrees C or 104 degrees F), reinforce the practicality of stockpiling and potentially utilizing the RiVax[®] vaccine in warfighters and civilian first responders without the complexities that arise for vaccines that require stringent cold chain handling.

RiVax[®] has been granted Orphan Drug designation as well as Fast Track designation by the FDA for the prevention of ricin intoxication. In addition, RiVax[®] has also been granted Orphan Drug designation in the European Union ("EU") from the EMA Committee for Orphan Medical Products.

Assuming development efforts are successful for RiVax[®], we believe potential government procurement contract(s) could reach as much as \$200 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

As a new chemical entity, an FDA approved RiVax[®] vaccine has the potential to qualify for a biodefense Priority Review Voucher ("PRV"). Approved under the 21st Century Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years of approximately \$100 million. When redeemed, PRVs entitle the user to an accelerated review period of nine months, saving a median of seven months review time as calculated in 2009. However, FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee (\$1.3 million for fiscal year 2024).

In July 2022, we signed a worldwide exclusive agreement to license and supply our ricin antigen, used in our RiVax[®] vaccine, to SERB, for development of a novel therapeutic treatment against ricin toxin poisoning. In pursuit of a ricin antidote, SERB will leverage its unique broad-spectrum polyclonal antibody platform, gained in its acquisition of BTG Specialty Pharmaceuticals. This specialized manufacturing process generates binding fragments from antibodies that are specific to a given antigen, helping to ensure potency and purity. This platform is currently used to manufacture two of SERB's currently marketed products, CroFab[®] and DigiFab[®].

In December 2022, we published a paper demonstrating statistically significant correlates of protection predicting survival after lethal aerosolized ricin challenge in non-human primates. The article titled "Serum antibody profiling identifies vaccine-induced correlates of protection against aerosolized ricin toxin in rhesus macaques" was published in the journal *npj Vaccines*.

Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigation Bioterror report released in November 2007 titled *Terrorism 2002-2005*, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations." Al Qaeda in the Arabian Peninsula had threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. In April 2013, letters addressed to the U.S. President, a Senator and a judge tested positive for ricin. As recently as September 2020, ricin-laced letters addressed to the White House and

others addressed to Texas law enforcement agencies were intercepted before delivery raising fresh concerns about the deadly toxin.

The Centers for Disease Control and Prevention has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield nor is there a known antidote for ricin toxin exposure.

SGX943 – for Treating Emerging and/or Antibiotic-Resistant Infectious Diseases

SGX943 is an IDR, containing the same active ingredient as SGX942. Dusquetide is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive in vivo preclinical studies have demonstrated enhanced clearance of bacterial infection with SGX943 administration. SGX943 has shown efficacy against both Gram-negative and Gram-positive bacterial infections in preclinical models, independent of whether the bacteria is antibiotic-resistant or antibiotic-sensitive.

The innate immune system is responsible for rapid and non-specific responses to combat bacterial infection. Augmenting these responses represents an alternative approach to treating bacterial infections. In animal models, IDRs are efficacious against both antibiotic-sensitive and antibiotic-resistant infections, both Gram-positive and Gram-negative bacteria, and are active irrespective of whether the bacteria occupy a primarily extracellular or intracellular niche. IDRs are also effective as stand-alone agents or in conjunction with antibiotics. An IDR for the treatment of serious bacterial infections encompasses a number of clinical advantages including:

- Treatment when antibiotics are contraindicated, such as:
 - o before the infectious organism and/or its antibiotic susceptibility is known; or
 - o in at-risk populations prior to infection.
- An ability to be used as an additive, complementary treatment with antibiotics, thereby:
 - o enhancing efficacy of sub-optimal antibiotic regimens (e.g., partially antibiotic-resistant infections);
 - o enhancing clearance of infection, thereby minimizing the generation of antibiotic resistance (e.g., in treating melioidosis); and
 - o reducing the required antibiotic dose, again potentially minimizing the generation of antibiotic resistance.
- An ability to modulate the deleterious consequences of inflammation in response to the infection, including the inflammation caused by antibiotic-driven bacterial lysis.
- Being unlikely to generate bacterial resistance since the IDR acts on the host, and not the pathogen.

Importantly, systemic inflammation and multi-organ failure is the ultimate common outcome of not only emerging and/or antibiotic-resistant infectious diseases, but also of most biothreat agents (e.g., *Burkholderia pseudomallei*), indicating that dusquetide would be applicable not only to antibiotic-resistant infection, but also

to biothreat agents, especially where the pathogen is not known and/or has been engineered for enhanced antibiotic resistance.

The Drug Approval Process

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements on the clinical development, manufacture and marketing of new drug and biologic products. The FDA, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended ("FDCA"), and other laws and comparable regulations for other agencies, regulate research and development activities and the testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale, export, import and distribution of such products. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including holds on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the U.S., refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

Before human clinical testing in the U.S. of a new drug compound or biological product can commence, an Investigational New Drug ("IND"), application is required to be submitted to the FDA. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit a NDA, for approval of a drug, or a Biologic License Application ("BLA"), for biologics such as vaccines, which will be reviewed, and if successful, approved by the FDA, allowing the product to be marketed. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of a NDA or BLA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. For certain drugs intended to treat serious, life-threatening conditions that show great promise in earlier testing, the FDA can also grant conditional approval. However, drug developers are required to study the drug further and verify clinical benefit as part of the conditional approval provision, and

the FDA can revoke approval if later testing does not reproduce previous findings. The FDA may also condition approval of a product on the sponsor agreeing to certain mitigation strategies that can limit the unfettered marketing of a drug. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

In the U.S., the FDCA, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern, or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the FDCA involving medical devices.

For biodefense development, such as with RiVax[®], the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use utilizing the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the benefit-risk scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

Vaccines are approved under the BLA process that exists under the Public Health Service Act. In addition to the greater technical challenges associated with developing biologics, the potential for generic competition is lower for a BLA product than a small molecule product subject to a NDA under the Federal Food, Drug and Cosmetic Act. Under the Patient Protection and Affordable Care Act enacted in 2010, a “generic” version of a biologic is known as a biosimilar and the barriers to entry – whether legal, scientific, or logistical – for a biosimilar version of a biologic approved under a BLA are higher.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan

drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic 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 or BLA application user fee.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

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 accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Paediatric Investigation Plan

As part of the regulatory process for the registration of new medicines with the EMA and the MHRA, pharmaceutical companies are required to provide a PIP outlining the Company's strategy for investigation of the new medicinal products in the paediatric population. In some instances, a waiver negating the need for a

PIP for certain conditions may be granted by the EMA or MHRA when development of a medicine for use in children is not feasible or appropriate.

Innovative Licensing and Access Pathway

The ILAP was launched in the UK at the start of 2021 to accelerate the development and access to promising medicines, thereby facilitating patient access to new medicines. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with the MHRA and other stakeholders including the NICE, and the SMC. The decision to award the Innovation Passport is made by an ILAP Steering Group, which is comprised of representatives from MHRA, NICE, and SMC. The Innovation Passport designation is the first step in the ILAP process and triggers the MHRA and its partner agencies to create a target development profile to chart out a roadmap for regulatory and development milestones with the goal of early patient access in the UK. Other benefits of ILAP include a 150-day accelerated assessment, rolling review and a continuous benefit risk assessment.

Early Access to Medicines Scheme

Launched in April 2014 in the United Kingdom by the MHRA, the Early Access to Medicines Scheme ("EAMS") offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines earlier than they would normally be accessible. PIM designation is the first phase of EAMS and is awarded following an assessment of early nonclinical and clinical data by the MHRA. The criteria product candidates must meet to obtain PIM designation are:

- Criterion 1 – The condition should be life-threatening or seriously debilitating with a high unmet medical need (i.e., there is no method of treatment, diagnosis or prevention available or existing methods have serious limitations).
- Criterion 2 – The medicinal product is likely to offer major advantage over methods currently used in the UK.
- Criterion 3 – The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

False Claims Laws

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government.

Anti-Kickback Laws

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

United States Healthcare Reform

Federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern 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.

Third-Party Suppliers and Manufacturers

Drug substance and drug product manufacturing is outsourced to qualified suppliers. We do not have manufacturing capabilities/infrastructure and do not intend to develop the capacity to manufacture drug products substances. We have agreements with third-party manufacturers to supply bulk drug substances for our product candidates and with third parties to formulate, package and distribute our product candidates. Our employees include professionals with expertise in pharmaceutical manufacturing development, quality assurance and third-party supplier management who oversee work conducted by third-party companies. We believe that we have on hand or can easily obtain sufficient amounts of product candidates to complete our currently contemplated clinical trials. All of the drug substances used in our product candidates currently are manufactured by single suppliers. While we have not experienced any supply disruptions, the number of manufacturers of the drug substances is limited. In the event it is necessary or advisable to acquire supplies from alternative suppliers, assuming commercially reasonable terms could be reached, the challenge would be the efficient transfer of technology and know-how from current manufactures to the new supplier. Formulation and distribution of our finished product candidates also currently are conducted by single suppliers but we believe that alternative sources for these services are readily available on commercially reasonable terms, subject to the efficient transfer of technology and know-how from current suppliers to the new supplier.

All of the current agreements for the supply of bulk drug substances for our product candidates and for the formulation or distribution of our product candidates relate solely to the development (including preclinical and clinical) of our product candidates. Under these contracts, our product candidates are manufactured upon our order of a specific quantity. In the event that we obtain marketing approval for a product candidate, we will qualify secondary suppliers for all key manufacturing activities supporting the marketing application.

Marketing and Collaboration

We do not currently have any sales and marketing capability, other than to potentially market our biodefense vaccine products directly to government agencies. With respect to other commercialization efforts, we currently intend to seek distribution and other collaboration arrangements for the sales and marketing of any product candidate that is approved, while also evaluating the potential to commercialize on our own in orphan disease

indications. From time to time, we have had and are having strategic discussions with potential collaboration partners for our biodefense vaccine product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidate on acceptable terms, if at all. We believe that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

On August 25, 2013, we entered into an agreement with SciClone, pursuant to which SciClone provided us with access to its oral mucositis clinical and regulatory data library in exchange for exclusive commercialization rights for SGX942 in the People's Republic of China, including Hong Kong and Macau, subject to the negotiation of economic terms. SciClone's data library was generated from two sequential Phase 2 clinical studies conducted in 2010 and 2012 evaluating SciClone's compound, SCV-07, for the treatment of oral mucositis caused by chemoradiation therapy in head and neck cancer patients, before SciClone terminated its program. By analyzing data available from the placebo subjects in the SciClone trials, we acquired valuable insight into disease progression, along with quantitative understanding of its incidence and severity in the head and neck cancer patient population. This information assisted us with the design of the SGX942 Phase 2 clinical trial, in which positive preliminary results were announced in December 2015.

On September 9, 2016, we and SciClone entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in the People's Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights. We also entered into a Common Stock purchase agreement with SciClone pursuant to which we sold 23,530 shares of our Common Stock to SciClone for approximately \$127.50 per share, for an aggregate price of \$3 million.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we do. Universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, also compete in the development of treatment technologies, and we face competition from other companies to acquire rights to those technologies.

HyBryte™ Competition

There is currently no approved cure for CTCL and treatments are prescribed to manage symptoms. The FDA has approved several treatments for later stages (IIB-IV) of CTCL and/or in conditions that are unresponsive to prior treatment. Three are targeted therapies (Targretin®-caps, Ontak® and Adcetris®), two are histone deacetylases inhibitors (Zolinda® and Istodax®) and the remaining two are topical therapies (Valchlor® and Targretin®-gel). There are currently no FDA approved therapies for the treatment of front-line, early stage (I-IIA) CTCL; however certain topical chemotherapies and topical, radiation, photodynamic and other therapies which are approved for indications other than CTCL are prescribed off-label for the treatment of early stage CTCL. These include narrow-band ultraviolet B (NB-UVB) light therapy and psoralen combined with ultraviolet A UVA light therapy ("PUVA"); however, PUVA treatments are usually limited to three times per week and 200 times in total due to the potentially carcinogenic side effect, while NB UVB is known to be effective against patches but less so against plaque lesions, common in early stage CTCL. There are other drugs currently in development that may have the potential to be used in early stage (I-IIA) CTCL, primarily in early Phase 1 and 2 clinical studies. Other treatments for later stage disease are not considered direct competitors.

SGX302 Competition

There is currently no approved cure for psoriasis and treatments are prescribed to manage symptoms. The FDA has approved several topical and systemic treatments for psoriasis. Systemic therapies dominate the treatment of severe and increasingly the more severe moderate patients, and include biologics aimed at reducing systemic inflammation. Skin directed therapy remains the primary treatment for mild-to-moderate disease. Current therapies for mild-to-moderate disease include psoralen activated by ultraviolet A ("PUVA", a photodynamic therapy), emollients, topical steroids, vitamin D preparations including retinoids (e.g., Sorilux®, Dovonex®, Cacitrene®), coal tar, salicylic acid, calcineurin inhibitors (e.g., Prograf®, Elidel®, Zorac®, Tazorac®) and dithranols (e.g., Drithocreme®). Other phototherapy approaches include the use of both broad-band and narrow-band ultraviolet B light. There are also a number of ongoing Phase 2 and 3 clinical trials in mild to moderate psoriasis.

Compared to PUVA, photoactivated hypericin uses non-carcinogenic and more penetrative visible light (unlike ultraviolet light used with PUVA) and a non-mutagenic compound hypericin (unlike psoralen used with PUVA), and is more highly targeted and more commensurate with long-term treatment. Compared to other skin-directed therapies, photoactivated hypericin has demonstrated a comparatively low local irritancy/adverse event rate with minimal long-term skin effects. Compared to systemic therapies, commonly used in more severe patients only, photoactivated hypericin does not cause immunosuppression.

SGX94/942/945 Competition

Because SGX94 (dusquetide) uses a novel mechanism of action in combating bacterial infections, there are no direct competitors at this time. Bacterial infections are routinely treated with antibiotics and SGX94 treatment is anticipated to be utilized primarily where antibiotics are insufficient (e.g., due to antibiotic resistance) or contra-indicated (e.g., in situations where the development of antibiotic resistance is a significant concern). Many groups are working on the antibiotic resistance problem and research into the innate immune system is intensifying, making emerging competition likely (from companies such as Celtaxsys Inc., Innaxon Therapeutics and Innate Pharma SA).

There is currently one drug approved for the treatment of oral mucositis in hematological cancer (palifermin). There are currently no approved drugs for treatment of oral mucositis in cancers with solid tumors (e.g., head and neck cancer). There are several drugs in clinical development for oral mucositis – three in Phase 3 (brilacidin by Innovation Pharmaceuticals, Inc., a mucobuccal tablet by Monopar Therapeutics LLC and GC4419 by Galera Therapeutics, Inc.). There are various natural products in small and/or open label studies (including sage, turmeric, honey and olive oil). In addition, there are medical devices approved for the treatment of oral mucositis including MuGard®, GelClair®, Episil®, and Caphosol®. These devices attempt to create a protective barrier around the oral ulceration with no biologic activity in treating the underlying disease.

There is currently no approved cure for BD and treatments are prescribed to manage symptoms. Treatments may include both maintenance therapies and those specifically addressing mucocutaneous flares (e.g., mouth ulcers, genital ulcers and leg ulcers). Corticosteroids are generally applied topically to sores and as eyedrops and may also be given systemically to reduce inflammation. Although used frequently, they have limited efficacy over the long-term and have significant side effects that become more concerning with more chronic use. Other treatments for BD flares involve suppressing the immune system with drugs (e.g., cyclosporine or cyclophosphamide). These drugs come with a higher risk of infection, liver and kidney problems, low blood counts and high blood pressure. For skin and mucosal manifestations of BD, anti-inflammatory drugs are also used, including colchicine, azathioprine, anti-TNF, anti-interferon alpha, anti-IL-17 and anti-IL-23 medications. The only approved drug in BD is apremilast, which is used as a maintenance therapy to prevent formation of oral ulcers. Apremilast is associated with both high cost and side effects including diarrhea, nausea, upper respiratory tract infection and headache.

ThermoVax® Competition

Multiple groups and companies are working to address the unmet need of vaccine thermostability using a variety of technologies. In addition, other organizations, such as the Bill and Melinda Gates Foundation and PATH, have programs designed to advance technologies to address this need.

Several stabilization technologies currently being developed involve mixing vaccine antigen +/- adjuvant with various proprietary excipients or co-factors that either serve to stabilize the vaccine or biological product in a liquid or dried (lyophilized) form. Examples of these approaches include the use of various plant-derived sugars and macromolecules being developed by companies such as iosBio. Variation Biotechnologies, Inc. ("VBI") is developing a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles ("VLPs"), and for potential application to a conventional influenza vaccine among others.

Additionally, companies like Altimmune, Inc., and Panacea Biotech Ltd., and Compass Biotech Inc. are developing proprietary vaccines with the application of some form of stabilization technology.

Public Health Solutions Competition

We face competition in the area of biodefense product development from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with our technologies.

The U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats is also developing a ricin vaccine candidate, RVEc™. RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were conducted to evaluate RVEc™'s safety as well as its immunogenicity, with positive results observed. No further data has been released in recent years. A monoclonal antibody is also being developed by Mapp Biopharmaceutical Inc. as a ricin therapeutic, with administration 4 hours after exposure demonstrating efficacy while administration 12 hours after ricin exposure was not protective in animal models.

There are no approved vaccines to prevent infection and/or mitigate exposure to Sudan ebolavirus or Marburg marburgvirus. There are other vaccine candidates in development, primarily using viral-vectored vaccine platforms. These platforms may be contra-indicated in the immune-compromised, pregnant individuals or children. They may also have limited efficacy on repeat administration.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

In 2014, we acquired a novel PDT that utilizes safe visible light for activation, which we refer to as HyBryte™. The active ingredient in HyBryte™ is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for HyBryte™ (U.S. patent 8,629,302) and additional issued and pending applications, both in the U.S. and abroad. U.S. patent 8,629,302 is expected to expire in September 2030. In August 2018, we were granted a U.S. patent (No. 10,053,513) titled "Systems and Methods for Producing Synthetic Hypericin." This newly issued patent, expected to expire in 2036, broadens the production around synthetic hypericin. Our proprietary formulation of synthetic hypericin also has been granted a European patent for the treatment of psoriasis, EP 2571507, and complements the method of treatment claims covered by the previously issued U.S. patent 6001882, Photoactivated hypericin and the use thereof. Further, on January 7, 2020, we also were granted a U.S. patent (No. 10,526,268) titled "Systems and Methods for Producing Synthetic Hypericin", which further expanded protection for the composition of purified synthetic hypericin. This patent is also expected to expire in 2036. Patent protection is also pursued worldwide with similar patents and expiry dates.

In addition to issued and pending patents, we also have "Orphan Drug" designations for HyBryte™ in the U.S. and the EU for CTCL, as well as for RiVax® in the U.S. and EU. Our Orphan Drug designations provide for seven years of post-approval marketing exclusivity in the U.S. and ten years exclusivity in Europe. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the U.S. seven year or EU ten year post-approval exclusivity provided by Orphan Drug legislation.

In 2013, we expanded our patent portfolio to include innate defense regulation through the acquisition of the novel drug technology, known as SGX94. By binding to the pivotal regulatory protein p62, also known as sequestosome-1, SGX94 regulates the innate immune system to reduce inflammation, eliminate infection and enhance healing. As part of the acquisition, we acquired all rights, including composition of matter patents for SGX94 as well as other analogs and crystal structures of SGX94 with its protein target p62, including U.S. patent 8,124,721 (expiring 2028), 9,416,157 (expiring 2028) and 8,791,061 (expiring 2029), both in the U.S. and abroad. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of University of British Columbia ("UBC"). We also have rights to the background technology patents (U.S. patent numbers 7,507,787 [expiring 2024], 7,687,454 [expiring 2026] and 11,311,598 [expiring 2034]). The U.S. Patent Office has also granted patents titled "Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis." The issued patents (U.S. patent numbers 9,850,279 and 10,253,068, both expiring in 2034) claim therapeutic use of dusquetide and related IDR analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the U.S. and worldwide.

ThermoVax® is the subject of U.S. patents 8,444,991 (expiring February 2030) and 8,808,710 (expiring March 2028) both issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition" and licensed to us by VitriVax, Inc. ThermoVax® is also U.S. patent application number 15/694,023 filed September 17, 2017 titled "Thermostable Vaccine Compositions and Methods of Preparing Same" and jointly invented by the UC and the Company. The patent application and the corresponding foreign filings are pending or granted and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable alum-adsorbed vaccines for ricin toxin and Ebola virus. An additional patent, covering vaccine combinations such as ricin toxin and anthrax, was filed in 2015 and granted on May 21, 2019 in the U.S. (No. 10,293,041, titled "Multivalent Stable Vaccine Composition and Methods of Making Same") and is expected to expire in 2035. A patent for unique, proprietary compositions and methods directed to combinations of glycoprotein antigens with nano-emulsion adjuvants comprising sucrose fatty acid esters prior to lyophilization was filed in 2020, granted in 2022 and expiring in 2040 (No. 11,433,129 titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines.") Patent protection is also pursued worldwide with similar patents and expiry dates.

Additional vaccine thermostabilization patents specific for anti-viral vaccines, including filovirus and coronavirus have been filed but are not yet granted. If granted, expiry dates would range from 2040 to 2041. Patent protection is also pursued worldwide with similar patents and expiry dates.

HyBryte™ License Agreement

In September 2014, we acquired a worldwide exclusive license agreement with New York University and Yeda Research and Development Company Ltd. for the rights to a novel PDT that utilizes safe visible light for activation, which we refer to as HyBryte™. To maintain this license, we are obligated to pay \$25,000 in annual license fees. In addition, we will pay the licensors: (a) a royalty amount equal to 3% of all net sales of HyBryte™ made directly by us and/or any affiliates; (b) a royalty amount equal to 2.5% of all net sales of HyBryte™ made by our sublicensees, subject to stated maximums and (c) 20% of all payments, not based on net sales, received by us from our sublicensees. This license may be terminated by either party upon notice of a material breach by the other party that is not cured within the applicable cure period. The exclusive license includes rights to several issued U.S. patents, including U.S. patent numbers 6,867,235 and 7,122,518, among other domestic and foreign patent applications. U.S. Patent numbers 6,867,235 and 7,122,518 expired in January 2020 and is expected to expire in November 2023, respectively.

We acquired the license agreement for HyBryte™ and related intangible assets, including U.S. patent 8,629,302, properties and rights pursuant to an asset purchase agreement with Hy Biopharma Inc. ("Hy Biopharma"). As consideration for the assets acquired, we initially paid \$275,000 in cash and issued 12,328 shares of Common Stock with a market value of \$3,750,000, and in March 2020 we issued 8,151 shares of Common Stock at a value of \$5,000,000 (based upon an effective per share price of \$614.40) as a result of HyBryte™ demonstrating statistical significant treatment response in the Phase 3 clinical trial. Provided the final success-orientated milestone is attained, we will be required to make a payment of up to \$5 million, if and when achieved, payable in our Common Stock.

SGX94 License Agreements

On December 18, 2012, we acquired a first in class drug technology, known as SGX94 (dusquetide), representing a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to reduce inflammation, eliminate infection and enhance tissue healing by binding to the pivotal regulatory protein p62, also known as sequestosome-1. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with UBC to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology. Under the license agreement we are obligated to pay UBC (i) an annual license maintenance fee of CAD \$1,000, and (ii) milestone payments which could reach up to CAD \$1.2 million. This license agreement (a) will automatically terminate if we file, or become subject to an involuntary filing, for bankruptcy, and (b) may be terminated by UBC in the event of, among other things, our insolvency, dissolution, grant of a security interest in the technology licensed to us pursuant to the license agreement, or material breach of or failure to perform material obligations under the license agreement or other research agreements between us and UBC.

ThermoVax® License Agreement

On December 21, 2010, we executed a worldwide exclusive license agreement with the UC for ThermoVax®, which is the subject of U.S. patent number 8,444,991 issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are licensed to us by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. U.S. Patent 8,444,991 is expected to expire in December 2031. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, we, in conjunction with UC, filed domestic and foreign patent applications claiming priority back to a provisional application filed on May 17, 2011 titled: "Thermostable Vaccine Compositions and Methods of Preparing Same." In April 2018, the UC delivered a notice of termination of our license agreement based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC, we and the UC agreed to extend the termination date to October 31, 2018 in order to allow us time to agree upon a potential agreement

that would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology in our field of use.

On October 31, 2018, in a series of related transactions, (a) we and the UC agreed to terminate the original license agreement, (b) the UC and VitriVax executed a worldwide exclusive license agreement for the heat stabilization technology for all fields of use, and (c) we and VitriVax executed a worldwide exclusive sublicense agreement, which was amended and restated in October 2020, for the heat stabilization technology for use in the fields of ricin and Ebola vaccines. We paid a \$100,000 sublicense fee on the effective date of the sublicense agreement. Under the amended sublicense agreement to maintain the sublicense we are obliged to pay a minimum annual royalty of \$20,000 until first commercial sale of a sublicensed product, upon which point, we will be required to pay an earned royalty of 2% of net sales subject to a minimum royalty of \$50,000 each year. We are also required to pay royalties on any sub-sublicense income based on a declining percentage of all sub-sublicense income calculated within the contractual period until reaching a minimum of 15% after two years. In addition, we are required to pay VitriVax milestone fees of: (a) \$25,000 upon initiation of a Phase 2 clinical trial of the sublicensed product, (b) \$100,000 upon initiation of a Phase 3 clinical trial of the sublicensed product, (c) \$100,000 upon regulatory approval of a sublicensed product, and (d) \$1 million upon achieving \$10 million in aggregate net sales of a sublicensed product in the U.S. or equivalent. To date none of these milestones have been met.

RiVax® License Agreement

In June 2003, we executed a worldwide exclusive option to license patent applications with UTSW for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine and, in October 2004, we negotiated the remaining oral rights to the ricin vaccine. To maintain this license, we are obligated to pay \$50,000 in annual license fees. Through this license, we have rights to the issued patent number 7,175,848 titled "Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin." This patent includes methods of use and composition claims for RiVax®.

CoVaccine HT™ License Agreement

In April 2020, we executed an agreement for the exclusive worldwide license of CoVaccine HT™, a novel vaccine adjuvant, from BTG, a division of Boston Scientific Corporation (NYSE: BSX), for the fields of SARS-CoV-2, the cause of COVID-19 and pandemic flu. The agreement was executed with Protherics Medicines Development, one of the companies that make up the BTG specialty pharmaceuticals business, which owns the CoVaccine HT™ intellectual property.

Research and Development Expenditures

We spent approximately \$1.1 million and \$0.9 million for the three months ended March 31, 2024 and 2023, respectively, and approximately \$3.3 million and \$7.9 million in the years ended December 31, 2023 and 2022, respectively, on research and development. The amounts we spent on research and development per product during the three months ended March 31, 2024 and 2023 and the years ended December 31, 2023 and 2022 are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

Human Capital

We are committed to a work environment that is welcoming, inclusive and encouraging. To achieve our plans and goals, it is imperative that we attract and retain top talent. In order to do so, we aim to have a safe and encouraging workplace, with opportunities for our employees to grow and develop professionally, supported by strong compensation, benefits, and other incentives. In addition to competitive base salaries, we offer every full-time employee a cash target bonus, a comprehensive benefits package and equity compensation.

As of March 31, 2024, we employed a total of 15 persons, including 2 part-time employees and 13 full-time employees, five of whom are MDs/PhDs. In addition to our employees, we contract with third-parties for the conduct of certain clinical development, manufacturing, accounting and administrative activities. We anticipate increasing the number of our employees. We have no collective bargaining agreements with our employees, and none are represented by labor unions. We consider our relationships with our employees to be good.

Throughout the COVID 19 pandemic, many of our employees have worked remotely. In September 2021 our employees returned to the Company's facilities in-person and have maintained a hybrid work schedule with both in-office and remote hours.

Properties

We currently lease approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey. This office space currently serves as our corporate headquarters, and both of our business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended from November 2022 to October 2025. The current rent is approximately \$11,367 per month and will remain so through October 2024. The rent for the lease period starting November 2024 is approximately \$11,625 per month. Our office space is sufficient for our current needs. We may add new space or expand existing space as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

MANAGEMENT

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of July 19, 2024.

Name	Age	Position
Christopher J. Schaber, PhD	57	Chairman of the Board, Chief Executive Officer and President
Gregg A. Lapointe, CPA, MBA	65	Director
Diane L Parks, MBA	71	Director
Robert J. Rubin, MD	78	Director
Jerome B. Zeldis, MD, PhD	74	Director
Jonathan Guarino, CPA, CGMA	52	Chief Financial Officer, Senior Vice President and Corporate Secretary
Oreola Donini, PhD	52	Chief Scientific Officer and Senior Vice President
Richard Straube, MD	72	Chief Medical Officer and Senior Vice President

Christopher J. Schaber, PhD has over 35 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board in October 2009. He also has served on the board of directors of the Biotechnology Council of New Jersey ("BioNJ") since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate council of the National Organization for Rare Disorders ("NORD") since October 2009. He also serves on the scientific advisory board for private start-up medical device company, Simphotek, Inc. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall

pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. During his career, Dr. Schaber has played a significant role in raising in excess of \$350 million through both public offerings and private placements, as well as approximately \$100 million in non-dilutive funding awards from state and federal governmental agencies. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as a senior executive officer with our Company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ and Simphotek; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Gregg A. Lapointe, CPA, MBA has been a director since March 2009. Mr. Lapointe is currently CEO of Cerium Pharmaceuticals, Inc. and serves on the board of directors of Rigel Pharmaceuticals, Inc., and Astria Therapeutics, Inc. Mr. Lapointe has previously served on the board of directors of ImmunoCellular Therapeutics Ltd., Raptor Pharmaceuticals, Inc., SciClone Pharmaceuticals, Inc., the Pharmaceuticals Research and Manufacturers of America (PhRMA), Questcor Pharmaceuticals, Inc. and the board of trustees of the Keck Graduate Institute of Applied Life Sciences. He previously served in varying roles for Sigma-Tau Pharmaceuticals, Inc. (now known as Leadiant Biosciences, Inc.), a private biopharmaceutical company, from September 2001 through February 2012, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer from April 2008 to February 2012. From May, 1996 to August 2001, he served as Vice President of Operations and Vice President, Controller of AstenJohnson, Inc. (formerly JWI Inc.). Prior to that, Mr. Lapointe spent several years in the Canadian medical products industry in both distribution and manufacturing. Mr. Lapointe began his career at Price Waterhouse. Mr. Lapointe received his B.A. degree in Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill University and his M.B.A. degree from Duke University. He is a C.P.A. in the state of Illinois. Mr. Lapointe was selected to serve as a member of our Board of Directors because of his significant experience in the areas of global strategic planning and implementation, business development, corporate finance, and acquisitions, and his experience as an executive officer and board member in the pharmaceutical and medical products industries.

Diane L. Parks, MBA has been a director since July 2019. From February 2016 until July 2018, she served as Head of U.S. Commercial and Senior Vice President of Marketing, Sales & Market Research at Kite Pharma, Inc., a privately-held biopharma company developing cancer immunotherapy products with a primary focus on genetically engineered autologous T cell therapy with chimeric antigen receptors. From October 2014 to October 2015, Ms. Parks served as Vice President of Global Marketing at Pharmacyclics LLC, a privately-held biopharmaceutical company primarily focused on the development of cancer therapies. Prior to Pharmacyclics LLC, Ms. Parks held senior leadership roles as Vice President of Sales for Amgen, Inc., a publicly-traded biopharmaceutical company, representing oncology and nephrology products, and Senior Vice President of Specialty Biotherapeutics and Managed Care at Genentech, Inc., a biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions that was acquired by Roche Holding AG in 2009. At Genentech, she led the launches of multiple products as well as commercial development of Lucentis® and Rituxan®. Since May 2019, she has been a member of the board of directors of Calliditas Therapeutics AB, a biopharmaceutical company, the shares of which are traded on the Nasdaq Stockholm Exchange, that is developing and commercializing pharmaceutical products for patients with significant unmet medical needs in niche indications. She is also a member of the board of directors of Kura Oncology, a biopharmaceutical company, the shares of which are traded on US Nasdaq, that is developing a pipeline of precision medicines for the treatment of solid tumors and

blood cancers. Since October 2019 Ms. Parks has been a member of the board of directors for TriSalus Life Sciences, an early stage company focused on improving patient outcomes in pancreatic and other highly intractable solid tumors. Ms. Parks holds a BS from Kansas State University and a master's of business administration in marketing from Georgia State University. She has been a commercial leader in the biotech and pharma industry for over 30 years. Ms. Parks was selected to serve as a member of our Board of Directors because of her over 30 years' experience as a businesswoman and commercial executive with an extensive record of driving profitable growth for large pharmaceutical and biotech companies.

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was President of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the U.S. Public Health Service. Dr. Rubin has served on the Board of BioTelemetry, Inc. (formerly known as CardioNet, Inc.) from 2007 to February 2021. He is currently on the Board of Cerium Pharmaceuticals where he is also the acting Chief Medical Officer since July 2022. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Jerome B. Zeldis, MD, PhD has been a director since June 2011. In March 2023 Dr. Zeldis retired as Executive Vice President, Research and Development of Neximmune. He was the Chief Medical Officer and President of Clinical Research, Drug Safety and Regulatory of Sorrento Therapeutics, Inc. and Celularity, Inc. Previously, Dr. Zeldis was Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company. He was employed by Celgene Corporation from 1997 to 2016. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical development. He has been a board member of several biotechnology companies and is currently on the boards of Metastat, Inc., PTC Therapeutics Inc., BioSig Technologies, Inc., the Castleman's Disease Organization and Alliqua, Inc. He has previously served on the boards of the NJ Chapter of the Arthritis Foundation and PTC Therapeutics, Inc. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School from July 1987 to September 1988, Associate Professor of Medicine at University of California, Davis from September 1988 to September 1994, Clinical Associate Professor of Medicine at Cornell Medical School from January 1995 to December 2003 and Professor of Clinical Medicine at the Robert Wood Johnson Medical School from July 1998 to June 2010. Dr. Zeldis received a BA and an MS from Brown University, and an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.

Jonathan Guarino, CPA, CGMA has been with our company since September 2019 and is currently our Senior Vice President and Chief Financial Officer. Mr. Guarino has had significant experience with both development-stage and commercial companies. From September 2016 to July 2019, he served as Corporate Controller for Hepion Pharmaceuticals, Inc. (formerly ContraVir Pharmaceuticals, Inc.), a New Jersey-based public biotechnology company, where he contributed to the establishment of the financial infrastructure, as well as assisted with capital fund-raising and debt financings. He worked as Controller for Suite K Value Added

Services LLC from August 2015 to September 2016 and as a senior manager of technical accounting for Covance, Inc., from June 2014 to May 2015. Prior to these positions, he held accounting and finance positions of increasing importance with several companies, including PricewaterhouseCoopers LLP, BlackRock, Inc. and Barnes & Noble, Inc. Mr. Guarino is a CPA (certified public accountant) and CGMA (chartered global management accountant), who received his BS in Business from Montclair State University.

Oreola Donini, PhD, has been with our company since August 2013 and is currently our Chief Scientific Officer and Senior Vice President, a position she has held since December 2014. Dr. Donini served as our Vice President of Preclinical Research and Development from August 2013 until December 2014. She has more than 20 years' experience in drug discovery and preclinical development with start-up biotechnology companies. From 2012 to 2013, Dr. Donini worked with ESSA Pharma Inc. as Vice President Research and Development. From 2004 to 2013, Dr. Donini worked with Inimex Pharmaceuticals Inc. ("Inimex"), lastly as Senior Director of Preclinical R&D from 2007 to 2013. Prior to joining Inimex, she worked with Kinetek Pharmaceuticals Inc., developing therapies for infectious disease, cancer and cancer supportive care. Dr. Donini is a co-inventor and leader of our SGX94 IDR technology, developed by Inimex and subsequently acquired by us. She was responsible for overseeing the manufacturing and preclinical testing of SGX94, which demonstrated efficacy in combating bacterial infections and mitigating the effects of tissue damage due to trauma, infection, radiation and/or chemotherapy treatment. These preclinical studies resulted in a successful Phase 1 clinical study and clearance of Phase 2 protocols for oral mucositis in head and neck cancer and acute bacterial skin and skin structure infections. While with ESSA Pharma Inc. as the Vice President of Research and Development, Dr. Donini led the preclinical testing of a novel N-terminal domain inhibitor of the androgen receptor for the treatment of prostate cancer. While with Kinetek Pharmaceuticals Inc., her work related to the discovery of novel kinase and phosphatase inhibitors for the treatment of cancer. Dr. Donini received her PhD from Queen's University in Kingston, Ontario, Canada and completed her post-doctoral work at the University of California, San Francisco. Her research has spanned drug discovery, preclinical development, manufacturing and clinical development in infectious disease, cancer and cancer supportive care.

Richard Straube, MD has been with our company since January 2014 and is currently our Senior Vice President and Chief Medical Officer. Dr. Straube is a board-certified pediatrician with over 35 years' experience in both academia and industry, including clinical research experience in host-response modulation. From 2009 until joining our company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. Prior to joining us, Dr. Straube served from 1988 to 1993 in various capacities, including most recently as Senior Director, Infectious Diseases and Immunology, Clinical Research, for Centocor, Inc., a privately-held biopharmaceutical company focused on developing monoclonal antibody-based diagnostics. While at Centocor, Inc., Dr. Straube was responsible for the initial anti-cytokine and anti-endotoxin programs targeted at ameliorating inappropriate host responses to infectious and immunologic challenges. Programs that he managed at Centocor, Inc. include assessments of immunomodulation using monoclonal removal of inciting molecular triggers, removal of internal immune-messengers, augmentation of normal host defenses, and maintenance of normal sub-cellular function in the face of injury. From 1993 to 1995, Dr. Straube was Director of Medical Affairs at T-cell Sciences, Inc., a privately-held biotechnology company. From 1995 to 1997, he was Director of Clinical Investigations of the Pharmaceutical Products Division of Ohmeda Corp., a privately-held biopharmaceutical company. He served from 1998 to 2007 as Executive Vice President of Research and Development and Chief Scientific Officer at INO Therapeutics LLC, a privately-held biotherapeutics company, where he was responsible for the clinical trials and subsequent approval of inhaled nitric oxide for the treatment of persistent pulmonary hypertension of the newborn. From 2007 to 2009, Dr. Straube was the Chief Medical Officer at Critical Biologics Corporation, a privately-held biotechnology company. Dr. Straube received his medical degree and residency training at the University of Chicago, completed a joint adult and pediatric infectious diseases fellowship at the University of California, San Diego ("UCSD"), and as a Milbank Scholar completed training in clinical trial design at the London School of Hygiene and Tropical Medicine. While on the faculty at the UCSD Medical Center, his research focused on interventional studies for serious viral infections.

Board Leadership Structure

Our Board of Directors believes that Dr. Schaber's service as both the Chairman of our Board of Directors and our Chief Executive Officer is in the best interest of our Company and our stockholders. Dr. Schaber possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing our Company and our business and, therefore, is best positioned to develop agendas that ensure that the Board of Directors' time and attention are focused on the most important matters. His combined role enables decisive leadership, ensures clear accountability, and enhances our ability to communicate our message and strategy clearly and consistently to our stockholders, employees, and collaborative partners.

Mr. Lapointe, Ms. Parks, Dr. Rubin, and Dr. Zeldis are independent and the Board of Directors believes that the independent directors provide effective oversight of management. Moreover, in addition to feedback provided during the course of meetings of the Board of Directors, the independent directors hold executive sessions. Following an executive session of independent directors, the independent directors' report back to the full Board of Directors regarding any specific feedback or issues, provide the Chairman with input regarding agenda items for Board of Directors and Committee meetings, and coordinate with the Chairman regarding information to be provided to the independent directors in performing their duties. The Board of Directors believes that this approach appropriately and effectively complements the combined Chairman/Chief Executive Officer structure.

Although we believe that the combination of the Chairman and Chief Executive Officer roles is appropriate under the current circumstances, our corporate governance guidelines do not establish this approach as a policy, and the Board of Directors may determine that it is more appropriate to separate the roles in the future.

Role of the Board of Directors in Risk Oversight

One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of our Board of Directors that address risks inherent in their respective areas of oversight. The Board of Directors is engaged in the oversight of risk through regular updates from Dr. Schaber, in his role as our Chief Executive Officer, and other members of our management team, regarding those risks confronting us (including risks relating to regulatory compliance, information technology and cybersecurity, environmental and sustainability, climate change and public health), the actions and strategies necessary to mitigate those risks and the status and effectiveness of those actions and strategies. The updates are provided at regularly scheduled Board of Directors and committee meetings as well as through more frequent informal meetings that include our Board of Directors, our Chief Executive Officer, our Chief Financial Officer, our Chief Medical Officer and our Chief Scientific Officer and other members of our management team. The Board of Directors provides insight into the issues, based on the experience of its members, and provides constructive challenges to management's assumptions and assertions.

In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure and our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.










Director Independence



The Board of Directors has determined that Mr. Lapointe, Ms. Parks, Dr. Rubin, and Dr. Zeldis are "independent" as such term is defined by the applicable listing standards of Nasdaq. Our Board of Directors

based this determination primarily on a review of the responses of the Directors to questionnaires regarding their employment, affiliations and family and other relationships.

Committees of the Board of Directors

Our Board of Directors has the following three committees: (1) Compensation, (2) Audit and (3) Nominating and Corporate Governance. Our Board of Directors has adopted a written charter for each of these committees, which are available on our website at www.soligenix.com under the "Investors" section.

Director	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Gregg A. Lapointe, CPA			
Diane L. Parks, MBA			
Robert J. Rubin, MD			
Jerome B. Zeldis, MD, PhD			

 – Committee Chair
 – Member

Audit Committee

Our Board of Directors has an Audit Committee, which is comprised of Mr. Lapointe (Chair), Ms. Parks and Dr. Rubin. The Audit Committee assists our Board of Directors in monitoring the financial reporting process, the internal control structure and the independent registered public accountants. Its primary duties are to serve as an independent and objective party to monitor the financial reporting process and internal control system, to review and appraise the audit effort of the independent registered public accountants and to provide an open avenue of communication among the independent registered public accountants, financial and senior management, and our Board of Directors. Our Board of Directors has determined that Mr. Lapointe, Ms. Parks and Dr. Rubin are "independent" directors, within the meaning of applicable listing standards of The Nasdaq Stock Market LLC ("Nasdaq") and the Exchange Act and the rules and regulations thereunder. Our Board of Directors has also determined that the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee and that Mr. Lapointe qualifies as an "audit committee financial expert" as that term is defined in the applicable regulations of the Exchange Act.

Compensation Committee

Our Board of Directors has a Compensation Committee, which is comprised of Dr. Rubin (Chair), Ms. Parks and Dr. Zeldis. The Compensation Committee is responsible for reviewing and approving the executive compensation program, assessing executive performance, setting salary, making grants of annual incentive compensation and approving certain employment agreements. Our Board of Directors has determined that Dr. Rubin, Mr. Lapointe and Dr. Zeldis are "independent" directors within the meaning of applicable listing standards of Nasdaq and the Exchange Act and the rules and regulations thereunder.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee ("Nominating Committee"), which is comprised of Dr. Zeldis (Chair), Mr. Lapointe and Dr. Rubin. The Nominating Committee makes recommendations to the Board of Directors regarding the size and composition of our Board of Directors, establishes procedures for the nomination process, identifies and recommends candidates for election to our

Board of Directors. Our Board of Directors has determined that Dr. Zeldis, Mr. Lapointe and Ms. Parks are “independent” directors, as such term is defined by the applicable Nasdaq listing standards.

Code of Ethics

We have adopted a code of ethics that applies to all our executive officers and senior financial officers (including our chief executive officer, chief financial officer, chief accounting officer and any person performing similar functions). A copy of our code of ethics is publicly available on our website at www.soligenix.com under the “Investors” section. If we make any substantive amendments to our code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our chief executive officer, chief financial officer or chief accounting officer, we will disclose the nature of such amendment or waiver in a Current Report on Form 8-K.

Diversity Considerations in Identifying Director Nominees

We do not have a formal diversity policy or set of guidelines in selecting and appointing directors that comprise our Board of Directors. However, when making recommendations to our Board of Directors regarding the size and composition of our Board of Directors, our Nominating Committee does consider each individual director’s qualifications, skills, business experience and capacity to serve as a director and the diversity of these attributes for the Board of Directors as a whole.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee is or has at any time during the past year been one of our officers or employees. None of our executive officers currently serves or in the past year has served as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

Clawback Policy

In 2023, we adopted a Clawback Policy in compliance with Nasdaq rules. Under our Clawback Policy, if we are required to prepare an accounting restatement due to material noncompliance with the financial reporting requirements under United States securities laws, we will be entitled to recover (and will seek to recover), from our executive officers, any excess incentive-based compensation received by our executive officers during the three-year period prior to the date on which we are required to prepare the restatement. This policy applies to both equity-based and cash compensation awards. The “excess compensation” is the difference between the actual amount that was paid and the amount that would have been paid if the financial statements were prepared properly in the first instance. To ensure that we can enforce the Clawback Policy, we require each executive officer subject to the policy to execute an acknowledgement stating that the executive has received and reviewed the policy and agrees that he or she is fully bound by the policy.

EXECUTIVE COMPENSATION

In 2024, in furtherance of our compensation philosophy and objectives, the Compensation Committee engaged Setren & Associates (“S&A”), an outside executive compensation consulting firm determined to be independent by the Compensation Committee, to conduct a review of, and recommend changes to, our compensation program for our executive officers. A representative of S&A attended Compensation Committee meetings at the invitation of the Compensation Committee Chairman and was also in direct contact with the Compensation Committee and our management from time to time. S&A provided the Compensation Committee with assistance and advice in the review of our salary structure, annual and equity incentive awards and other related executive pay issues. In addition, S&A provided advice regarding marketplace trends and best practices relating to competitive pay levels.

S&A did not provide any services to us other than its services as the Compensation Committee’s independent compensation consultant, and S&A did not receive any fees or compensation from us other than the fee it

received as the independent compensation consultant. SS&A did not provide any services to us in 2023. The Compensation Committee confirmed that S&A's work for the Compensation Committee did not create any conflicts of interest.

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2023 and 2022, respectively to our Chief Executive Officer and each of the three other most highly compensated executive officers (collectively, the "Named Executive Officers").

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber ⁽¹⁾	CEO &	2023	\$ 519,476	\$ 72,727	\$ 75,482	\$ 32,800	\$ 700,484
	President	2022	\$ 499,496	\$ 107,891	\$ 73,059	\$ 30,740	\$ 711,185
Jonathan Guarino ⁽²⁾	CFO &	2023	\$ 245,000	\$ 31,605	\$ 45,289	\$ 32,800	\$ 354,693
	Senior VP	2022	\$ 231,132	\$ 42,436	\$ 51,042	\$ 30,740	\$ 355,350
Oreola Donini ⁽³⁾	CSO &	2023	\$ 300,000	\$ 37,800	\$ 45,289	\$ 4,505	\$ 387,594
	Senior VP	2022	\$ 280,800	\$ 51,555	\$ 27,259	\$ 4,628	\$ 364,242
Richard C. Straube ⁽⁴⁾	CMO &	2023	\$ 189,461	\$ 22,736	\$ 37,741	\$ —	\$ 249,938
	Senior VP	2022	\$ 182,174	\$ 32,901	\$ 27,259	\$ —	\$ 242,334

- (1) Dr. Schaber deferred the payment of his 2023 bonus of \$72,727 until January 15, 2024. Option awards figure includes the value of Common Stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.
- (2) Mr. Guarino deferred the payment of his 2023 bonus of \$31,605 until January 15, 2024. Option awards figure includes the value of Common Stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.
- (3) Dr. Donini deferred the payment of her 2023 bonus of \$37,800 until January 15, 2024. Option awards figure includes the value of Common Stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.
- (4) Dr. Straube deferred the payment of his 2023 bonus of \$22,736 until January 15, 2024. Option awards figure includes the value of Common Stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of \$300,000 per year and a minimum annual bonus of \$100,000. Dr. Schaber's employment agreement automatically renews every three years, unless otherwise terminated, and last was automatically renewed in December 2019 for an additional term of three years. We agreed to issue him options to purchase 833 shares of our Common Stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any

accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber's monetary compensation (base salary of \$300,000 and bonus of \$100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of the company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

In January 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to increase the number of shares of Common Stock from 334 to 33,334, issuable to Dr. Schaber immediately prior to the completion of a transaction or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party.

In December 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to modify the severance terms. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber twelve months of severance, as well as a pro rata bonus calculated by the average of his prior two year's annual bonuses, if any, and based on the number of months that he was employed during the year in which his employment was terminated; however, in the case of termination without "Just Cause" within one year following a change in control or the sale or other disposition of all or substantially all of our assets Dr. Schaber will be entitled 18 months of severance and health insurance and life insurance benefits for him and his dependents.

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Schaber to \$499,496. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Schaber to \$519,476. On December 8, 2023, the Compensation Committee approved an increase in salary for Dr. Schaber to \$540,255.

In July 2013, we entered into a one-year employment agreement with Oreola Donini, PhD, our Vice President Preclinical Research & Development. Pursuant to the agreement, we agreed to pay Dr. Donini \$170,000 (CAD) per year and a targeted annual bonus of 20% of base salary. We also issued her options to purchase 2,666 shares of our Common Stock with one-quarter immediately vesting and the remainder vesting over three years. Dr. Donini's employment agreement automatically renews each year, unless otherwise terminated, and has automatically renewed each year since execution. Upon termination without "Just Cause", as defined in Dr. Donini's employment agreement, we would pay Dr. Donini three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. In December 2014, Dr. Donini was named Chief Scientific Officer and Senior Vice President. Upon Dr. Donini's promotion to Chief Scientific Officer, the Compensation Committee increased her targeted bonus to 30% of her annual base salary. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Donini to \$280,800. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Donini to \$300,000. On December 8, 2023, the Compensation Committee approved an increase in salary for Dr. Donini to \$312,000.

In December 2014, we entered into a one-year employment agreement with Richard C. Straube, MD, our Chief Medical Officer and Senior Vice President. Pursuant to the agreement, we agreed to pay Dr. Straube \$300,000 per year and a targeted annual bonus of 30% of base salary. We also issued him options to purchase 666 shares of our Common Stock with one-third immediately vesting and the remainder vesting over three years. On March 26, 2019, we entered into an amendment to our employment agreement with Dr. Straube. Pursuant to the amended agreement, which amendment becomes effective as of April 1, 2019, Dr. Straube will be required to devote at least 20 hours per week to the performance of his duties and we will pay him \$170,000 per year. The amended employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in the amended employment agreement, we would pay

Dr. Straube one month of severance. No unvested options vest beyond the termination date. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Straube to \$182,174. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Straube to \$189,461. On December 8, 2023, the Compensation Committee approved an increase in salary for Dr. Straube to \$197,039.

On September 9, 2019, we entered into a one-year employment agreement with Jonathan Guarino, CPA, CGMA, our Senior Vice President and Chief Financial Officer. Pursuant to the agreement, we agreed to pay Mr. Guarino \$220,000 per year and a targeted annual bonus of 30% of base salary. We also issued him options to purchase 2,666 shares of our Common Stock with one-quarter immediately vesting and the remainder vesting over three years. Mr. Guarino's employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in Mr. Guarino's employment agreement, we would pay Mr. Guarino three months of severance, accrued salary, bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 10, 2021, the Compensation Committee approved an increase in salary for Mr. Guarino to \$231,132. On December 8, 2022, the Compensation Committee approved an increase in salary for Mr. Guarino to \$245,000. On December 8, 2023, the Compensation Committee approved an increase in salary for Mr. Guarino to \$254,800.

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2023. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable			
Christopher J. Schaber	41	—	—	\$ 3,600.00	12/04/2024
	58	—	—	\$ 2,712.00	12/30/2025
	250	—	—	\$ 640.80	12/06/2027
	250	—	—	\$ 232.80	12/12/2028
	250	—	—	\$ 230.40	01/01/2029
	250	—	—	\$ 297.60	12/11/2029
	250	—	—	\$ 348.00	01/01/2030
	250	—	—	\$ 561.60	12/09/2030
	239	11	11	\$ 307.20	01/03/2031
	191	59	59	\$ 187.20	12/08/2031
	52	—	—	\$ 165.60	01/02/2032
	122	122	75	\$ 165.60	01/02/2032
	294	294	289	\$ 129.60	12/07/2032
	2,344	2,344	7,031	\$ 10.72	12/07/2033
Jonathan Guarino	166	—	—	\$ 232.80	09/08/2029
	41	—	—	\$ 297.60	12/11/2029
	166	—	—	\$ 561.60	12/09/2030
	208	143	65	\$ 187.20	12/08/2031
	333	168	165	\$ 129.60	12/07/2032
	5,625	1,407	4,218	\$ 10.72	12/07/2033
Oreola Donini	12	—	—	\$ 3,600	12/04/2024
	29	—	—	\$ 2,712	12/30/2025
	83	—	—	\$ 640.80	03/30/2027
	145	—	—	\$ 482.40	12/06/2027
	166	—	—	\$ 232.80	12/12/2028
	250	—	—	\$ 297.60	12/11/2029
	291	—	—	\$ 561.60	12/09/2030
	291	225	66	\$ 187.20	12/08/2031
	333	168	165	\$ 129.60	12/07/2032
	5,625	1,407	4,218	\$ 10.72	12/07/2033
Richard C. Straube	41	—	—	\$ 4,824.00	01/06/2024
	20	—	—	\$ 3,600	12/04/2024
	29	—	—	\$ 2,712	12/30/2025
	83	—	—	\$ 640.80	03/30/2027
	145	—	—	\$ 482.40	12/06/2027
	166	—	—	\$ 232.80	12/12/2028
	125	—	—	\$ 297.60	12/11/2029
	166	—	—	\$ 561.60	12/09/2030
	166	130	36	\$ 187.20	12/08/2031
	333	168	165	\$ 129.60	12/07/2032
	4,687	1,172	3,515	\$ 10.72	12/07/2033

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the year ended December 31, 2023.

Name	Fees Earned Paid in Cash (1)	Option Awards (2)	Total
Gregg A. Lapointe	\$ 55,000	\$ 22,500	\$ 77,500
Diane L. Parks	\$ 47,500	\$ 22,500	\$ 70,000
Robert J. Rubin	\$ 57,500	\$ 22,500	\$ 80,000
Jerome B. Zeldis	\$ 50,000	\$ 22,500	\$ 72,500
Timothy Cote (3)	\$ 6,435	\$ 21,300	\$ 27,735

- (1) Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid \$35,000 annually, on a prorated basis, for their service on our Board of Directors, the chairman of our Audit Committee is paid \$15,000 annually, on a prorated basis, and the chairmen of our Compensation and Nominating Committees is paid \$10,000 annually, on a prorated basis. Additionally, Audit Committee members are paid \$7,500 annually and Compensation and Nominating Committee members are paid \$5,000 annually. This compensation is paid quarterly.
- (2) We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 15,000 shares of Common Stock. Upon re-election to the Board, each Board member will receive stock options with a value of \$30,000, calculated using the closing price of the Common Stock on the trading day prior to the date of the annual meeting of our stockholders, which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders. Our Board of Directors determined to reduce the number of stock options issuable upon reelection in 2023 by 25% to \$22,500.
- (3) Dr. Cote was appointed by our Board of Directors in May 2023 and resigned, for personal reasons, as a member of our Board of Directors on July 7, 2023.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Our audit committee is responsible for the review, approval and ratification of related party transactions. The audit committee reviews these transactions under our Code of Ethics, which governs conflicts of interests, among other matters, and is applicable to our employees, officers and directors.

We have granted registration rights to certain stockholders, including the Selling Stockholders. These registration rights give the stockholders the right to require that we register its shares under the Securities Act for sale to the public, subject to certain conditions. Certain stockholders also have piggyback registration rights, which means that, if not already registered, they have the right to include their shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses incurred in connection with the exercise of these demand registration rights.

We are unable to estimate the dollar value of the registration rights to the holders of these rights. The amount of reimbursable expenses depends on a number of variables, including whether registration rights are exercised incident to a primary offering by us, the form on which we are eligible to register such a transaction, and whether we have a shelf registration in place at the time of a future offering.

On April 27, 2023, we entered into an exclusive option agreement with Silk Road Therapeutics, Inc. ("Silk Road"), pursuant to which Silk Road granted us an exclusive option to purchase all assets and rights, including intellectual property and regulatory documents, related to Silk Road's PTX product candidate, a non-biological anti-TNF-alpha inhibitor, for the treatment of mucocutaneous ulcers in patient's suffering from Behçet's Disease ("BD"). The option agreement expired on August 25, 2023. In consideration for the option, we paid \$50,000 of cash and issued 31,646 shares of Common Stock with a value of \$50,000. The consideration paid for the option was recorded as general and administrative expense on the accompanying consolidated statements of operations. As of August 25, 2023, we concluded our due diligence activities and decided to allow the option to expire. A member of our Board of Directors has an ownership interest in Silk Road.

Other than as described above, the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2022.

SECURITY OWNERSHIP OF MANAGEMENT AND OTHER BENEFICIAL OWNERS

The table below provides information regarding the beneficial ownership of the Common Stock as of July 19, 2024, of each of our directors, each of the Named Executive Officers, and our directors and officers as a group. As of July 19, 2024, we are not aware of any person beneficially owning more than 5% of our outstanding Common Stock. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of Common Stock held by them.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned **	Percent of Class
Christopher J. Schaber ⁽¹⁾	6,557	*
Gregg A. Lapointe ⁽²⁾	1,879	*
Diane L. Parks ⁽³⁾	1,821	*
Robert J. Rubin ⁽⁴⁾	1,867	*
Jerome B. Zeldis ⁽⁵⁾	1,944	*
Jonathan Guarino ⁽⁶⁾	3,735	*
Oreola Donini ⁽⁷⁾	3,665	*
Richard Straube ⁽⁸⁾	3,100	*
All directors and executive officers as a group (8 persons) (9)	24,568	1.57%

- (1) Includes 379 shares of Common Stock and options to purchase 6,178 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (2) Includes 31 shares of Common Stock and options to purchase 1,848 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (3) Includes 63 shares of Common Stock and options to purchase 1,758 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Ms. Parks is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (4) Includes 19 shares of Common Stock and options to purchase 1,848 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

- (5) Includes 96 shares of Common Stock and options to purchase 1,848 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (6) Includes 46 shares of Common Stock and options to purchase 3,689 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Mr. Guarino is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (7) Includes options to purchase 3,665 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Dr. Donini is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (8) Includes 34 shares of Common Stock and options to purchase 3,066 shares of Common Stock exercisable within 60 days of July 19, 2024. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.
- (9) Includes 668 shares of Common Stock and options to purchase 23,900 shares of Common Stock exercisable within 60 days of July 19, 2024.
- * Indicates less than 1%.
- ** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of Common Stock subject to options or warrants currently exercisable or exercisable within 60 days of July 19, 2024 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 2,280,108 shares of Common Stock outstanding as of July 19, 2024.

SELLING STOCKHOLDERS

We have prepared this prospectus to allow the Selling Stockholders to sell or otherwise dispose of, from time to time, up to 1,054,688 Resale Shares.

On July 9, 2024, we entered into the Warrant Inducement Agreement with the Selling Stockholders, who were the holders of certain existing Warrants to Purchase Shares of Common Stock ("Existing Warrants"). Pursuant to the Warrant Inducement Agreement, the Selling Stockholders agreed to exercise for cash their Existing Warrants to purchase up to 703,125 shares of our Common Stock at an exercise price of \$6.00 per share (which includes the \$0.125 charge for the July 2024 Warrants in compliance with the Nasdaq rules) during the period from the date of the Warrant Inducement Agreement until 1:00 p.m., Eastern Time, on July 9, 2024.

In consideration of the Selling Stockholders' agreement to exercise the Existing Warrants in accordance with the Warrant Inducement Agreement, we agreed to issue the July 2024 Warrants to purchase shares of Common Stock equal to 150% of the number of shares of Common Stock issued upon exercise of the Existing Warrants. We agreed in the Warrant Inducement Agreement to register for resale by the Selling Stockholders the Resale Shares underlying the July 2024 Warrants and have filed with the SEC a registration statement on Form S-1, of which this prospectus forms a part, with respect to the resale or other disposition of the securities offered from time to time by the Selling Stockholders under this prospectus. We will not receive any of the proceeds from sales by the Selling Stockholders of any of the Resale Shares covered by this prospectus.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares of our Common Stock. Unless otherwise indicated below, to our knowledge, the Selling Stockholders named in the table below have sole voting and investment power with respect to the

shares of Common Stock beneficially owned by them. The number of shares of Common Stock beneficially owned prior to the offering for each Selling Stockholder includes (i) all shares of our Common Stock held by such Selling Stockholder prior to the transactions contemplated by the Warrant Inducement Agreement plus (ii) all shares of our Common Stock (or pre-funded warrants in lieu of) issued to such Selling Stockholder pursuant to our April 22, 2024 public offering, as well as (iii) all shares of our Common Stock that may be received by such Selling Stockholder pursuant to the transactions contemplated by the Warrant Inducement Agreement and being offered pursuant to the prospectus. The inclusion of any shares in this table does not constitute an admission of beneficial ownership by the person named below.

The beneficial ownership information presented in the table below is as of July 19, 2024. The Selling Stockholders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of their shares of Common Stock since the date on which the information in the table below is presented. Information about the Selling Stockholders may change over time.

Name of Selling Stockholder	Number of Common Shares Beneficially Owned Prior to Offering (1)	Maximum Number of Common Shares to be Sold Pursuant to this Prospectus (2)	Number of Common Shares Beneficially Owned After Offering (3)	Percentage Beneficially Owned After Offering (3)
Armistice Capital, LLC. (4)	937,500	937,500	—	—
Bigger Capital Fund, LP (5)	46,875	46,875	—	—
District 2 Capital Fund LP (5)	46,875	46,875	—	—
Patrick F. Keogh (6)	29,710	23,483	—	—

- (1) The beneficial ownership prior to this offering number for each investor includes the following:
 - a. Armistice Capital, LLC: 937,500 shares of Common Stock underlying the July 2024 Warrants.
 - b. Bigger Capital Fund, LP: 46,875 shares of Common Stock underlying the July 2024 Warrants.
 - c. District 2 Capital Fund LP.: 46,875 shares of Common Stock underlying the July 2024 Warrants.
 - d. Patrick F. Keogh: 29,710 Common Stock held by the Selling Stockholder, including 23,483 shares of Common Stock underlying the July 2024 Warrants.
- (2) The warrants, and the underlying Resale Shares, are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Stockholders from exercising that portion of the warrants that would result in the Selling Stockholders and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation.
- (3) Because the Selling Stockholders may sell, transfer or otherwise dispose of all, some or none of the Resale Shares covered by this prospectus, we cannot determine the number of such shares that will be sold, transferred or otherwise disposed of by the Selling Stockholders, or the amount or percentage of our Common Stock that will be held by the Selling Stockholders upon completion of this offering. For purposes of this table, we have assumed that the Selling Stockholders will sell all their Resale Shares covered by this Prospectus, including shares issuable upon exercise of the July 2024 Warrants and the remaining pre-funded warrants issued in connection to our April 22, 2024 public offering.
- (4) The securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

- (5) Bigger Capital Fund GP, LLC ("Bigger GP") is a general partner of Bigger Capital Fund, LP ("Bigger Capital") and District 2 Capital LLC ("District 2") is the investment manager of District 2 Capital Fund LP ("District 2 CF"). Michael Bigger is the managing member of Bigger GP and District 2 and District 2 Holdings LLC ("District 2 Holdings"), which is the managing member of District 2 GP LLC ("District 2 GP"), the general partner of District 2 CF. Therefore, Mr. Bigger, District 2, District 2 Holdings and District 2 CF may be deemed to be the beneficial owner, and have the shared power to dispose of or direct the disposition, of the shares reported as beneficially owned by District 2 CF and Mr. Bigger and Bigger GP may be deemed to be the beneficial owner, and have the shared power to dispose of or direct the disposition, of the shares reported as beneficially owned by Bigger Capital and District 2 CF. The address of Bigger Capital is 11434 Glowing Sunset, Las Vegas, Nevada 89135 and the address of District 2 CF is 114175 West Carver Street, Huntington, New York 11743.
- (6) The address of Patrick F. Keogh is P.O. Box 1128, Frisco, Colorado 80443.

Certain Relationships and Related Party Transactions

On July 9, 2024, we entered into the Warrant Inducement Agreement with the Selling Stockholders, who were the holders of the Existing Warrants. Pursuant to the Warrant Inducement Agreement, the Selling Stockholders agreed to exercise for cash their Existing Warrants to purchase up to 703,125 shares of our Common Stock at an exercise price of \$6.00 per share (which includes the \$0.125 charge for the July 2024 Warrants in compliance with the Nasdaq rules) during the period from the date of the Warrant Inducement Agreement until 1:00 p.m., Eastern Time, on July 9, 2024.

In connection with the Warrant Inducement Agreement, we received aggregate gross proceeds of approximately \$4,218,750 million from the exercise of the Existing Warrants, before deducting financial advisory fees and other expenses payable by us. Upon the exercise of the Existing Warrants by the Selling Stockholders in accordance with the Warrant Inducement Agreement, we issued the July 2024 Warrants to purchase shares of Common Stock equal to 150% of the number of shares of Common Stock issued upon exercise of the Existing Warrants. We anticipate receiving aggregate gross proceeds of up to approximately \$6,328,128 million if the July 2024 Warrants are issued and exercised.

Pursuant to the Warrant Inducement Agreement, we agreed to file a registration statement on Form S-1 to register the resale of the Resale Shares upon exercise of the July 2024 Warrants by July 25, 2024, and to use commercially reasonable efforts to have such registration statement declared effective by the SEC within ninety (90) days following the date of filing the registration statement and to keep the registration statement effective at all times until no holder of the July 2024 Warrants owns any July 2024 Warrants or Resale Shares. In the event that the Company fails to timely deliver to the holder the Resale Shares without restrictive legends, the Company agreed to pay certain liquidated damages to the Selling Stockholders. We are registering the shares to be sold by the Selling Stockholders under the registration statement of which this prospectus is a part to satisfy our obligation under the Warrant Inducement Agreement.

On April 17, 2024, we entered into a Securities Purchase Agreement with the certain of the Selling Stockholders and other purchasers, pursuant to which we issued and sold to certain of the Selling Stockholders (i) 3,275,000 shares of Common Stock, (ii) pre-funded warrants to purchase up to an aggregate of 8,600,000 shares of Common Stock (the "April 2024 Pre-funded Warrants"), and (iii) common warrants to purchase up to an aggregate of 11,875,000 shares of Common Stock (together with the April 2024 Pre-funded Warrants, the "April 2024 Warrants"). The Existing Warrants that are subject to the Warrant Inducement Agreement consist of the April 2024 Warrants.

PLAN OF DISTRIBUTION

The Selling Stockholders, and their pledgees, donees, transferees or other successors in interest, may from time to time offer and sell, separately or together, some or all of the Resale Shares covered by this prospectus. Registration of the Resale Shares covered by this prospectus does not mean, however, that those Resale Shares necessarily will be offered or sold.

The Resale Shares covered by this prospectus may be sold from time to time, at market prices prevailing at the time of sale, at prices related to market prices, at a fixed price or prices subject to change or at negotiated prices, by a variety of methods including the following:

- in the Nasdaq Capital Market;
- in privately negotiated transactions;
- through broker-dealers, who may act as agents or principals;
- through one or more underwriters on a firm commitment or best-efforts basis;
- in a block trade in which a broker-dealer will attempt to sell a block of securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- directly to one or more purchasers;
- through agents; or
- in any combination of the above.

In effecting sales, brokers or dealers engaged by the Selling Stockholders may arrange for other brokers or dealers to participate. Broker-dealer transactions may include:

- purchases of the Resale Shares by a broker-dealer as principal and resales of the Resale Shares by the broker-dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions; or
- transactions in which the broker-dealer solicits purchasers on a best efforts basis.

To our knowledge, the Selling Stockholders have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the Resale Shares covered by this prospectus. At any time a particular offer of the securities covered by this prospectus is made, a revised prospectus or prospectus supplement, if required, will be distributed which will set forth the aggregate amount of Resale Shares covered by this prospectus being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers or agents. In addition, to the extent required, any discounts, commissions, concessions and other items constituting underwriters' or agents' compensation, as well as any discounts, commissions or concessions allowed or reallocated or paid to dealers, will be set forth in such revised prospectus supplement. Any such required prospectus supplement, and, if necessary, a post-effective amendment to the registration statement of which this prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the securities covered by this prospectus.

DESCRIPTION OF CAPITAL STOCK

The following description of the terms of our securities is not complete and is qualified in its entirety by reference to our Certificate of Incorporation, and our Bylaws, as amended (the "Bylaws"), both of which are filed as exhibits to the registration statement of which this prospectus forms a part.

Under our Certificate of Incorporation and Bylaws, we are authorized to issue 75,350,000 shares of capital stock, consisting of 75,000,000 shares of Common Stock, par value \$0.001 per share, 230,000 shares of undesignated preferred stock (none of which are currently outstanding), 10,000 shares of Series B Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), 10,000 shares of Series C Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), and 100,000 shares of Series A Junior Participating Preferred Stock, par value \$0.001 per share (none of which are currently outstanding).

All outstanding shares of Common Stock are validly issued, fully paid, and nonassessable.

Common Stock

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held in the election of directors and in all other matters to be voted on by stockholders. There is no cumulative voting in the election of directors. The affirmative vote of the holders of a plurality of the shares of Common Stock represented at an annual meeting is required to elect each director.

Dividends and Liquidation Rights

Holders of Common Stock are entitled to receive dividends as may be declared from time to time by our Board of Directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the Company, holders of Common Stock are to share in all assets remaining after the payment of liabilities.

Conversion, Redemption and Other Rights

Holders of Common Stock have no pre-emptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the Common Stock. The rights of the holders of the Common Stock are subject to any rights that may be fixed for holders of preferred stock.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 230,000 shares of undesignated preferred stock, 10,000 shares of Series B Convertible Preferred Stock, par value \$0.05 per share (the "Series B Preferred Stock"), 10,000 shares of Series C Convertible Preferred Stock, par value \$0.05 per share (the "Series C Preferred Stock"), and 100,000 shares of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the "Junior Preferred Stock"). Our Board of Directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock with dividend, liquidation, conversion, voting or other rights, including the right to issue convertible securities with no limitations on conversion, which could adversely affect the voting power or other rights of the holders of our Common Stock, substantially dilute a Common Stockholder's interest and depress the price of our Common Stock.

No shares of the Series B Preferred Stock, the Series C Preferred Stock or the Junior Preferred Stock are outstanding. Due to the terms of the Series C Preferred Stock, no additional shares of Series C Preferred Stock can be issued.

Series B Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 10,000 shares of Series B Preferred Stock, none of which are outstanding and 6,411 of which have been converted to Common Stock and therefore are not reissuable.

Voting Rights

Each holder of Series B Preferred Stock is entitled to the number of votes equal to the number of whole shares of Common Stock into which the shares of Series Preferred Stock held by such holder is then convertible (as adjusted from time to time pursuant to our Certificate of Incorporation) with respect to any and all matters presented to the stockholders for their action or consideration. Except as provided by law, holders of Series B Preferred Stock vote together with the holders of Common Stock as a single class.

Dividends and Liquidation Rights

The holders of the Series B Preferred Stock are entitled to a dividend of 8% per annum, payable annually in shares of Series B Preferred Stock. In addition, when and if our Board of Directors shall declare a dividend payable with respect to the then outstanding shares of Common Stock, the holders of the Series B Preferred Stock are entitled to the amount of dividends per share as would be payable on the largest number of whole shares of Common Stock into which each share of Series B Preferred Stock could then be converted.

In the event of liquidation, dissolution or winding up of the Company, the holders of Series B Preferred Stock then outstanding will be entitled to be paid an amount equal to \$1,000 per share (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares pursuant to our Certificate of Incorporation), plus any dividends declared but unpaid thereon before any payment is made to the holders of Common Stock, Junior Preferred Stock or any other class or series of stock ranking on liquidation junior to the Series B Preferred Stock. After the holders of the Series B Preferred Stock have been paid in full, the remaining assets of the Company will be distributed to the holders of Junior Preferred Stock and Common Stock, subject to the preferences of the Junior Preferred Stock.

Conversion, Redemption and Other Rights

Each share of Series B Preferred Stock is convertible into 1.333 shares of Common Stock. The conversion ratio is subject to an adjustment upon the issuance of additional shares of Common Stock for a price below the closing price of the Common Stock and equitable adjustment for stock splits, dividends, combinations, reorganizations and similar events.

Subject to certain conditions, after the second anniversary of the issuance of the Series B Preferred Stock, the Company will have the right, but not the obligation, to redeem the then-outstanding shares of Series B Preferred Stock for cash in an amount calculated pursuant to the terms of our Certificate of Incorporation.

Junior Preferred Stock

Voting Rights

The holders of the Junior Preferred Stock will have 10,000 votes per share of Junior Preferred Stock on all matters submitted to a vote of our stockholders, including the election of directors.

Dividends and Liquidation Rights

If our Board of Directors declares or pays dividends on Common Stock, the holders of the Junior Preferred Stock would be entitled to receive a per share dividend payment of 10,000 times the dividend declared per share of Common Stock. In the event we make a distribution on the Common Stock, the holders of the Junior

Preferred Stock will be entitled to a per share distribution, in like kind, of 10,000 times such distribution made per share of Common Stock. In the event of any merger, consolidation or other transaction in which shares of Common Stock are exchanged, each share of Junior Preferred Stock will be entitled to receive 10,000 times the amount received per share of Common Stock. These rights are protected by customary anti-dilution provisions.

Upon any liquidation, dissolution or winding up, no distribution may be made to the holders of shares of stock ranking junior to the Junior Preferred Stock unless the holders of the Junior Preferred Stock have received the greater of (i) \$37.00 per one one-thousandth share plus an amount equal to accrued and unpaid dividends and distributions thereon, and (ii) an amount equal to 10,000 times the aggregate amount to be distributed per share to holders of Common Stock. Further, no distribution may be made to the holders of stock ranking on a parity upon liquidation, dissolution or winding up with the Junior Preferred Stock, unless distributions are made ratably on the Junior Preferred Stock and all other shares of such parity stock in proportion to the total amounts to which the holders of the Junior Preferred Stock are entitled above and to which the holders of such parity shares are entitled.

Anti-Takeover Provisions

Provisions in our Certificate of Incorporation and Bylaws may discourage certain types of transactions involving an actual or potential change of control of our company which might be beneficial to us or our security holders.

As noted above, our Certificate of Incorporation permits our Board of Directors to issue shares of any class or series of preferred stock in the future without stockholder approval and upon such terms as our Board of Directors may determine. The rights of the holders of Common Stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Our Bylaws generally provide that any board vacancy, including a vacancy resulting from an increase in the authorized number of directors, may be filled by a majority of the directors, even if less than a quorum.

Additionally, our Bylaws provide that stockholders must provide timely notice in writing to bring business before an annual meeting of shareholders or to nominate candidates for election as directors at an annual meeting of shareholders. Notice for an annual meeting is timely if our secretary receives the written notice not less than 45 days and no more than 75 days prior to the anniversary of the date that we mailed proxy materials for the preceding year's annual meeting. However, if the date of the annual meeting is advanced more than thirty (30) days prior to, or delayed by more than thirty (30) days after, the anniversary of the preceding year's annual meeting, notice by the stockholder to be timely must be delivered not later than the close of business on the later of (i) the 90th day prior to such annual meeting or (ii) the 10th day following the day on which public announcement of the date of such annual meeting is first made. Our Bylaws also specify the form and content of a shareholder's notice. These provisions may prevent shareholders from bringing matters before an annual meeting of shareholders or from making nominations for directors at an annual meeting of shareholders.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL") regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our Board of Directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or
- at or subsequent to the date of the transaction, the business combination is approved by our Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our Board of Directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of Common Stock held by stockholders.

Forum Selection Provisions

As permitted by the DGCL, our Bylaws require, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, that the Court of Chancery of the State of Delaware, shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the company, (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, other employee or stockholder of the company to the company or the our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine.

Further, our Bylaws provided that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Exclusions or Limitations to Forum Selection Provisions

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, the exclusive forum provisions in our Bylaws do not apply to claims arising under the Exchange Act. The forum selection provisions, however, are intended to apply to the fullest extent permitted by law, including to actions or claims arising under the Securities Act. However, it is possible that a court could find our forum selection provisions to be inapplicable or unenforceable with respect to actions or claims arising under the Securities Act. Even if a court accepts that our forum selection provisions apply to actions or claims arising under the Securities Act, our stockholders shall not be deemed to have waived compliance with the federal securities laws and the rules and regulations thereunder.

Transfer Agent

The transfer agent and registrar for our Common Stock is Equiniti Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, NY 11219 and its telephone number is (718) 921-8200.

Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "SNGX."

LEGAL MATTERS

The validity of the securities being offered will be passed upon for us by Duane Morris LLP, Boca Raton, Florida.

EXPERTS

The consolidated balance sheet of Soligenix, Inc. and subsidiaries as of December 31, 2023, and the related consolidated statements of operations, comprehensive loss, changes in mezzanine equity and shareholders' equity (deficit), and cash flows for the year then ended, have been audited by Cherry Bekaert LLP, independent registered public accounting firm, as stated in their report, which is included herein, which report includes an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern. Such financial statements have been included herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated balance sheet of Soligenix, Inc. and subsidiaries as of December 31, 2022, and the related consolidated statements of operations, comprehensive loss, changes in mezzanine equity and shareholders' equity (deficit), and cash flows for the year then ended, before the effects of the adjustments to retrospectively apply the reverse stock split in Note 13, have been audited by EisnerAmper LLP ("EisnerAmper"), independent registered public accounting firm, as stated in their report which is included herein, which report includes an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern. Such financial statements have been included herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing. Soligenix, Inc. and subsidiaries have agreed to indemnify and hold EisnerAmper harmless against and from any and all legal costs and expenses incurred by EisnerAmper in successful defense of any legal action or proceeding that arises as a result of EisnerAmper's consent to the inclusion of its audit report on the Company's past financial statements included in this registration statement.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a resale registration statement on Form S-1 under the Securities Act for the Resale Shares being offered by this prospectus. This prospectus, which is part of the registration statement, does not contain all of the information included in the registration statement and the exhibits. For further information about us and the Resale Shares offered by this prospectus, you should refer to the registration statement and its exhibits. References in this prospectus to any of our contracts or other documents are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. Additionally, we file annual, quarterly and current reports, proxy statements and other information with the SEC.

The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including us, at <http://www.sec.gov>. We make available, free of charge, on our website at www.soligenix.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports and statements as soon as reasonably practicable after they are filed with the SEC. The contents of our and the SEC's websites are not part of this prospectus, and the reference to our and the SEC's websites do not constitute incorporation by reference into this prospectus of the information contained at those sites.

SOLIGENIX, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
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PART I - FINANCIAL INFORMATION
ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,091,548	\$ 8,446,158
Contracts and grants receivable	117,029	—
Unbilled revenue	—	171,254
Research and development incentives receivable, current	25,253	23,894
Deferred issuance cost	132,681	—
Prepaid expenses and other current assets	451,876	866,014
Total current assets	7,818,387	9,507,320
Security deposit	22,777	22,777
Office furniture and equipment, net	10,339	11,927
Right-of-use lease assets	200,569	229,834
Research and development incentives receivable, net of current portion	6,313	25,468
Total assets	<u>\$ 8,058,385</u>	<u>\$ 9,797,326</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,436,728	\$ 1,111,226
Accrued expenses	2,602,665	2,418,002
Accrued compensation	50,216	251,115
Lease liabilities, current	125,143	121,765
Convertible debt	2,996,136	2,250,000
Total current liabilities	7,210,888	6,152,108
Non-current liabilities:		
Convertible debt	—	1,010,934
Lease liabilities, net of current portion	79,125	111,862
Total liabilities	<u>7,290,013</u>	<u>7,274,904</u>
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, 350,000 shares authorized; none issued or outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$.001 par value; 75,000,000 shares authorized; 657,900 and 648,761 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively ⁽¹⁾	658	649
Additional paid-in capital ⁽¹⁾	228,363,074	228,203,706
Accumulated other comprehensive income	24,143	22,243
Accumulated deficit	(227,619,503)	(225,704,176)
Total shareholders' equity	768,372	2,522,422
Total liabilities and shareholders' equity	<u>\$ 8,058,385</u>	<u>\$ 9,797,326</u>

⁽¹⁾ Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
For the Three Months Ended March 31, 2024 and 2023
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Grant revenue	\$ 117,029	\$ 257,178
Total revenues	117,029	257,178
Cost of revenues	(117,029)	(226,040)
Gross profit	—	31,138
Operating expenses:		
Research and development	1,095,040	946,451
General and administrative	1,022,051	1,235,376
Total operating expenses	2,117,091	2,181,827
Loss from operations	(2,117,091)	(2,150,689)
Other income (expense):		
Foreign currency transaction gain (loss)	1,209	(366)
Interest income (expense), net	28,842	(103,568)
Research and development incentives	6,331	6,448
Other income	—	40,869
Change in fair value of convertible debt	165,382	—
Total other income (expense)	201,764	(56,617)
Net loss before income taxes	(1,915,327)	(2,207,306)
Income tax benefit	—	1,161,197
Net loss applicable to common stockholders	\$ (1,915,327)	\$ (1,046,109)
Basic and diluted net loss per share ⁽¹⁾	\$ (2.42)	\$ (5.74)
Basic and diluted weighted average common shares outstanding ⁽¹⁾	790,239	182,296

⁽¹⁾ Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Loss
For the Three Months Ended March 31, 2024 and 2023
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Net loss	\$ (1,915,327)	\$ (1,046,109)
Other comprehensive income (loss):		
Foreign currency translation adjustments	1,900	(12,153)
Comprehensive loss	<u>\$ (1,913,427)</u>	<u>\$ (1,058,262)</u>

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

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Shareholders' Equity/(Deficit)
For the Three Months Ended March 31, 2024 and 2023
(Unaudited)

	Mezzanine Equity-Series D Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2023	—	\$ —	648,761	\$ 649	\$228,203,706	\$ 22,243	\$(225,704,176)	\$ 2,522,422
Issuance of common stock associated with conversion of debt			9,139	9	99,407	—	—	99,416
Share-based compensation expense			—	—	59,961	—	—	59,961
Foreign currency translation adjustment			—	—	—	1,900	—	1,900
Net loss			—	—	—	—	(1,915,327)	(1,915,327)
Balance, March 31, 2024	—	\$ —	657,900	\$ 658	\$228,363,074	\$ 24,143	\$(227,619,503)	\$ 768,372

	Mezzanine Equity-Series D Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2022	—	\$ 43	181,898	\$ 182	\$217,067,691	\$ 24,747	\$(219,563,446)	\$(2,470,826)
Sale of common stock pursuant to B. Riley At Market Issuance Sales Agreement			1,329	1	70,729	—	—	70,730
Issuance costs associated with B. Riley At Market Issuance Sales Agreement			—	—	(2,341)	—	—	(2,341)
Redemption of Series D preferred stock	—	(43)						—
Share-based compensation expense			—	—	73,634	—	—	73,634
Foreign currency translation adjustment			—	—	—	(12,153)	—	(12,153)
Net loss			—	—	—	—	(1,046,109)	(1,046,109)
Balance, March 31, 2023	—	\$ —	183,227	\$ 183	\$217,209,713	\$ 12,594	\$(220,609,555)	\$(3,387,065)

Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2024 and 2023
(Unaudited)

	2024	2023
Operating activities:		
Net loss	\$ (1,915,327)	\$ (1,046,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	1,588	1,785
Non-cash lease expense	29,265	26,936
Share-based compensation	59,961	73,634
Change in fair value of convertible debt	(165,382)	—
Amortization of deferred issuance costs associated with convertible debt	—	10,242
Change in operating assets and liabilities:		
Contracts and grants receivable	54,225	(102,878)
Prepaid expenses and other current assets	414,138	60,894
Research and development incentives receivable	17,379	98,456
Operating lease liability	(29,359)	(26,256)
Accounts payable and accrued expenses	391,929	(970,757)
Accrued compensation	(200,899)	(292,200)
Net cash used in operating activities	(1,342,482)	(2,166,253)
Financing activities:		
Proceeds from issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement	—	70,730
Costs associated with B. Riley At Market Issuance Sales Agreement	—	(2,288)
Deferred issuance costs associated with public offering	(8,992)	—
Convertible debt repayments	—	(1,000,000)
Net cash used in financing activities	(8,992)	(931,558)
Effect of exchange rate on cash and cash equivalents	(3,136)	4,046
Net decrease in cash and cash equivalents	(1,354,610)	(3,093,765)
Cash and cash equivalents at beginning of period	8,446,158	13,359,615
Cash and cash equivalents at end of period	\$ 7,091,548	\$ 10,265,850
Supplemental information:		
Cash paid for state income taxes	\$ 17,965	\$ 2,110
Cash paid for interest	\$ 64,047	\$ 213,490
Cash paid for lease liabilities:		
Operating lease	\$ 34,100	\$ 33,325
Non-cash investing and financing activities:		
Pontifax conversion of portion of debt principal into common stock	\$ 99,416	—
Deferred issuance cost reclassified to additional paid-in capital	\$ —	\$ 53
Redemption liability for Series D preferred stock	\$ —	\$ 43
Public offering costs included in accounts payable	\$ 123,689	\$ —

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

Soligenix, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company") is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: Specialized BioTherapeutics and Public Health Solutions.

The Company's Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin sodium), a novel photodynamic therapy utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"). With agreement from the European Medicines Agency ("EMA") on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early-stage disease, the Company is targeting to begin patient enrollment by the end of 2024 with top-line results anticipated in the second half of 2026. Upon successful completion of the second Phase 3 study, called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2), regulatory approval will be sought to support potential commercialization worldwide.

Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, the Company's first-in-class innate defense regulator technology, and dusquetide (SGX942 and SGX945) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer and aphthous ulcers in Behçet's Disease.

The Company's Public Health Solutions business segment includes development programs for RiVax®, its ricin toxin vaccine candidate and SGX943, its therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, its vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of the vaccine programs incorporates the use of the Company's proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority and the Defense Threat Reduction Agency.

The Company primarily generates revenues under government grants and contracts. The Company was awarded a subcontract that originally provided for approximately \$1.1 million from a U.S. Food and Drug Administration ("FDA") Orphan Products Development grant over four years for an expanded study of HyBryte™ in the treatment of CTCL. The Company will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the FDA regulations, and other regulatory authorities, litigation, and product liability.

Results for the three months ended March 31, 2024 are not necessarily indicative of results that may be expected for the full year.

Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued. As of March 31, 2024, the Company had an accumulated deficit of \$227,619,503. During the three months ended March 31, 2024, the Company incurred a net loss of \$1,915,327 and used \$1,342,482 of cash in operating activities. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be determined largely by the budgeted operational expenditures incurred in regards to the progression of its product candidates. Management believes that the Company has sufficient resources available to support its development activities.

and business operations and timely satisfy its obligations as they become due through the first quarter of 2025. The Company does not have sufficient cash and cash equivalents as of the date of filing this Quarterly Report on Form 10-Q to support its operations for at least the 12 months following the date the financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern through 12 months after the date the financial statements are issued.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, the Company plans to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of the common stock via an At Market Issuance Sales Agreement and potentially amending the loan agreement with Pontifax Medison Finance ("Pontifax") to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce the Company's debt repayments; however, none of these alternatives are committed at this time. There can be no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to it to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that it will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, the Company will not have sufficient cash resources and liquidity to fund its business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms when needed may require the Company to delay, limit, or eliminate the development of business opportunities and its ability to achieve its business objectives and its competitiveness, and its business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce the Company's ability to access capital, which could negatively affect its liquidity and ability to continue as a going concern. In addition, the perception that the Company may not be able to continue as a going concern may cause others to choose not to deal with it due to concerns about its ability to meet its contractual obligations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of March 31, 2024, the Company had cash and cash equivalents of \$ 7,091,548 as compared to \$8,446,158 as of December 31, 2023, representing a decrease of \$1,354,610 or 16%. As of March 31, 2024, the Company had working capital of \$607,499 as compared to working capital of \$ 3,355,212 as of December 31, 2023, representing a decrease in working capital of \$2,747,713 or 82%. The decrease in cash and cash equivalents was primarily related to cash used in operating activities during the three months ended March 31, 2024. The decrease in working capital is primarily the result of the reclassification of approximately \$1 million of the Company's convertible debt balance from a non-current liability as of December 31, 2023 to a current liability as of March 31, 2024 (resulting from the amendment to the loan and security agreement with Pontifax – see Note 4), and cash used in operating activities during the three months ended March 31, 2024.

Management's business strategy can be outlined as follows:

- Following agreement from the EMA on the key design components for the second confirmatory Phase 3 placebo-controlled FLASH2 clinical trial of HyBryte™ in CTCL and positive primary endpoint results from the first Phase 3 FLASH study, initiate the FLASH2 study, while at the same time, continuing discussions with the FDA on potential modifications to the development path to adequately address their feedback.
- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.
- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 (dusquetide) in the treatment in oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.

- Expanding development of dusquetide under the research name SGX945 into Behçet's Disease with the conduct of a Phase 2a clinical trial, where previous studies with dusquetide in oral mucositis have validated the biologic activity in aphthous ulcers induced by chemotherapy and radiation.
- Continue development of the Company's heat stabilization platform technology, ThermoVax[®], in combination with its programs for RiVax[®] (ricin toxin vaccine), and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses and multivalent combinations), with United States ("U.S.") government or non-governmental organization funding support.
- Continue to apply for and secure additional government funding for the Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.
- Pursue business development opportunities for pipeline programs, as well as explore all strategic alternatives, including but not limited to merger/acquisition strategies.
- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

The Company's plans with respect to its liquidity management include, but are not limited to, the following:

- The Company has up to approximately \$673,000 in active government grant funding still available as of March 31, 2024 to support its associated research programs through May 2026, provided the federal agencies do not elect to terminate the grants for convenience. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies. However, there can be no assurance that the Company will obtain additional governmental grant funding.
- The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.
- The Company will continue to pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program if the program is available.
- The Company plans to pursue potential partnerships for pipeline programs as well as continue to explore merger and acquisition strategies. However, there can be no assurances that the Company can consummate such transactions.
- The Company completed a public offering on April 22, 2024 of 204,694 shares of its common stock, pre-funded warrants to purchase 537,500 shares of its common stock and common warrants to purchase up to 742,194 shares of its common stock at a combined public offering price of \$6.40. The pre-funded warrants have an exercise price of \$0.02. The common warrants have an exercise price of \$6.40 per share, are exercisable immediately and expire five years from the issuance date. The total gross proceeds to the Company from this offering were approximately \$4.75 million before deducting commissions and other estimated offering expenses (\$4.3 million, net). The Company plans to use the proceeds for further support of its programs, as well as for working capital. See Note 8.
- The Company is currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Nasdaq Capital Market Listing Requirements

On June 23, 2023, the Company received a letter from the staff (the "Staff") of the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between May 9, 2023 through June 22, 2023, the Company did not meet the minimum bid price of \$1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that the Company would be provided with a compliance period of 180 calendar days, or until December 20,

2023, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A). The Company was unable to regain compliance prior to the expiration of the 180-day period.

On December 21, 2023, the Company received another written notice (the "Notice") from the Staff stating that the Company had not complied with the minimum bid price requirement and was not eligible for a second 180-day period because the Company did not comply with the \$5,000,000 minimum stockholders' equity initial listing requirement for Nasdaq. As a result, the Notice indicated that the Company's common stock would be suspended from trading on Nasdaq unless the Company requested a hearing before the Nasdaq Hearings Panel by December 28, 2023. On March 26, 2024, the Company had an oral hearing with a Nasdaq Hearings Panel to appeal the Staff's delisting determination, which stayed the trading suspension of the Common Stock pending a final written decision by the Nasdaq Hearings Panel and expiration of any additional extension period granted by the panel following the hearing.

In order to regain compliance with Nasdaq's minimum bid price requirement, the Company's common stock must maintain a minimum closing bid price of \$1.00 for at least ten consecutive business days during the compliance period.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision-making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: Specialized BioTherapeutics and Public Health Solutions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

Contracts and grants receivable consist of amounts due from various grants from the NIH and contracts from NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for credit losses has been established. If amounts become uncollectible, they are charged to operations.

Impairment of Long-Lived Assets

Office furniture and equipment and right of use assets with finite lives are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the three months ended March 31, 2024 and 2023.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on March 31, 2024. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
- Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

The carrying amounts reported in the condensed consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, research and development incentives receivable, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

The carrying amount reported in the condensed consolidated balance sheet as of March 31, 2024 for the convertible debt is its fair value - see Note 4. The principal amount of the convertible debt was \$2,900,585 at March 31, 2024 and the fair value was \$ 2,996,136. The fair value of the debt was estimated using the Monte Carlo valuation method, which utilizes certain unobservable inputs. As a result, the fair value estimate represents a Level 3 measurement.

A roll forward of the carrying value of the convertible debt to March 31, 2024 is as follows:

	Balance December 31, 2023	Conversion January 3, 2024	Adjustment to fair value	Balance March 31, 2024
Convertible debt at fair value	\$ 3,260,934	\$ (99,416)	\$ (165,382)	\$ 2,996,136

Deferred Issuance Costs

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

Revenue Recognition

The Company's revenues include revenues generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

The Company also records revenue from contracts with customers in accordance with Accounting Standards Codification Topic 606 ("ASC 606"), *Revenue From Contracts with Customers*. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Certain amounts received from or billed to customers in accordance with contract terms are deferred and recognized as future performance obligations are satisfied. All amounts earned under contracts with customers other than sales-based royalties are classified as licensing revenue. Sales-based royalties under the Company's license agreements would be recognized as royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. These options have a ten-year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed under the Company's 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, restricted stock, deferred stock and unrestricted stock to the Company's employees and non-employees (including consultants). The shares issued under the 2015 Plan are registered on Form S-8 (SEC File No. 333-208515). However, as shares of common stock are not covered by a reoffer prospectus, the certificates reflecting such shares reflect a Securities Act of 1933, as amended restrictive legend. Stock compensation expense for equity-classified awards to non-employees is measured on the date of grant and is recognized when the services are performed.

There were no options issued during the three months ended March 31, 2024 and 2023.

Foreign Currency Transactions and Translation

In accordance with FASB ASC 830 *Foreign Currency Matters*, the UK subsidiary expresses its U.S. dollar and Euro denominated transactions in its functional currency, the British Pound, with related transaction gains or losses included in net loss. On a quarterly basis, the financial statements of the UK subsidiary are translated into U.S. dollars and consolidated into the Company's financials, with related translation adjustments reported as a cumulative translation adjustment ("CTA"), which is a component of accumulated other comprehensive income. During the three months ended March 31, 2024 and 2023, the Company recognized a foreign currency transaction gain of \$1,209 and a foreign currency transaction loss of (\$ 366), respectively, in the accompanying condensed consolidated statements of operations.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company did not recognize an income tax benefit during the three months ended March 31, 2024. The Company recognized \$1,161,197 of income tax benefit, net of transaction costs from the sale of its 2021 NOL carryforwards during the three months ended March 31, 2023. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for the three months ended March 31, 2024 and 2023. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2024 or December 31, 2023.

Loss Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Included within the Company's weighted average common shares outstanding for the three months ended March 31, 2024, are common shares issuable upon the exercise of the pre-funded warrants associated with the May 2023 public offering, as these pre-funded warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

The following table summarizes potentially dilutive adjustments to the number of common shares which were excluded from the diluted calculation because their effect would be anti-dilutive due to the losses in each period:

	As of March 31,	
	2024	2023
Common stock purchase warrants	408,640	—
Stock options	56,568	11,946
Convertible debt	335,716	105,746
Total	800,924	117,692

The weighted average exercise prices of the Company's warrants and stock options outstanding at March 31, 2024 were \$ 24.00 and \$87.15 per share, respectively. The weighted average exercise prices of the Company's stock options outstanding at March 31, 2023 was \$435.32 per share. The weighted average conversion price of the Company's convertible debt at March 31, 2024 and 2023 was \$138.24 and \$453.92 per share, respectively.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles in the U.S. ("GAAP") requires management to make estimates and assumptions such as the fair value of warrants and stock options and to accrue for clinical trials in process that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Note 3. Accrued Expenses

The following is a summary of the Company's accrued expenses:

	March 31, 2024	December 31, 2023
Clinical trial expenses	\$ 2,070,955	\$ 1,993,784
Other	531,710	424,218
Total	\$ 2,602,665	\$ 2,418,002

Note 4. Debt

In December 2020, the Company entered into a \$ 20 million convertible debt financing agreement with Pontifax. Under the terms of the agreement with Pontifax, the Company had access to up to \$20 million in convertible debt financing in three tranches, which will mature on June 15, 2025 and had an interest-only period for the first two years with a fixed interest rate of 8.47% on borrowed amounts and an interest rate of 1% on amounts available but not borrowed as an unused line of credit fee. After the interest-only period, the outstanding principal was to be repaid in quarterly payments of \$1 million each commencing in the first quarter of 2023. The agreement is secured by a lien covering substantially all of the Company's assets, other than intellectual property.

Upon the closing of this transaction, the Company borrowed the first tranche of \$ 10 million, had the option to draw the second tranche of \$5 million at any time during the initial 12 months of the loan and the third tranche of \$ 5 million upon filing of the new drug application for HyBryte™, subject to certain conditions. The Company elected to let the options to borrow both the second and third tranches expire as of December 15, 2021 and March 15, 2022, respectively.

On April 19, 2023, the Company entered into an amendment to the convertible debt financing agreement dated December 15, 2020 with Pontifax. The amendment called for the immediate payment of \$5 million of the outstanding principal balance and any accrued interest, waived any prepayment charge in connection with the repayment of this amount and resulted in an outstanding principal balance of \$3 million. The amendment also provided for a new interest only period from the date of the amendment through June 30, 2024, reduced quarterly principal repayments from \$1 million to \$750,000 and eliminated the minimum cash covenant. Further, the amendment reduced the conversion price with respect to the remaining principal amount under the agreement to (i) 90% of the closing price of the Company's common stock on the day before the delivery of the conversion notice with respect to the first 36,790 shares of the Company's common stock issuable upon conversion and to (ii) \$27.20 with respect to all shares of the Company's common stock issuable upon conversion in excess of the first 36,790 shares so issued. The remaining terms of the agreement remain in effect without modification.

On January, 3, 2024, Pontifax delivered a conversion notice to the Company electing to convert a portion of the remaining principal balance into shares of the Company's common stock. Upon conversion, the Company issued 9,139 shares of the Company's common stock at \$10.88 per share, reducing the remaining principal balance by \$99,416. Pontifax may elect to convert the remaining outstanding loan drawn under the first tranche into additional shares of the Company's common stock at any time prior to repayment. The Company also has the ability to force the conversion of the loan into shares of its common stock, subject to certain conditions.

The amendment to the convertible debt financing agreement with Pontifax resulted in the extinguishment of the original convertible debt for accounting purposes. The Company concluded that the amended debt instrument has an embedded derivative that requires bifurcation pursuant to ASC 815-15-25-1 and qualifies for the fair value option in accordance with ASC 815-15-25-4 through ASC 815-15-25-6. The Company elected to account for the amended convertible debt using the fair value option, which requires the Company to record changes in fair value as a component of other income or expense. The fair value of the convertible debt as of March 31, 2024 was \$2,996,136, which resulted in the recognition of \$ 165,382 of other income from the change in the fair value of the convertible debt on the Company's accompanying condensed consolidated statements of operations during the three months ended March 31, 2024. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

The key assumptions used in the Monte Carlo valuations were as follows:

Assumptions	12/31/2023	3/31/2024
Stock price	\$ 0.76	\$ 0.60
Volatility	141.90%	148.80%
Discount rate	13.62%	16.16%
Risk-free rate	4.65%	5.03%

Interest expense incurred during the three months ended March 31, 2024 and 2023 was \$ 61,239 and \$187,964, respectively. Interest expense paid during the three months ended March 31, 2024 and 2023 was \$64,047 and \$213,490, respectively.

Annual principal and interest payments due as of March 31, 2024 in accordance with the amended terms of the Pontifax loan agreement, including the January 3, 2024 conversion and assuming no further conversions are as follows:

Year	Principal	Interest	Total
Remainder of 2024	\$ 2,250,000	\$ 198,305	\$ 2,448,305
2025	650,585	13,889	664,474
Total	\$ 2,900,585	\$ 212,194	\$ 3,112,779

Note 5. Shareholders' Equity

Common Stock

The following items represent transactions in the Company's common stock for the three months ended March 31, 2024:

- The Company issued Pontifax 9,139 shares of fully vested common stock pursuant to conversion of a portion of the convertible debt principal balance at a conversion price of \$10.88 per share on January 3, 2024, the date of issuance. The conversion price was based on 90% of the closing price of the Company's common stock on the day before the delivery of the conversion notice.

The issuance of the Company's common stock in connection with the convertible debt financing agreement as described above was exempt under Section 3(a)(9) of the Securities Act of 1933, as amended.

Note 6. Commitments and Contingencies

Contractual Obligations

The Company has commitments of approximately \$230,000 as of March 31, 2024 over the next five years for several licensing agreements with partners and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to approximately \$13.2 million, royalties on net sales of covered products ranging from 2% to 3% sub-license Investigational New Drug ("IND") milestones on covered products of up to approximately \$200,000, sub-license income royalties on covered products up to 15% and sub-license global net sales royalties on covered products ranging from 1.5% to 2.5%, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

The Company currently leases office space which serves as the Company's corporate headquarters, and both of the Company's business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended to October 2025. The current rent of \$11,367 per month will be maintained until November 2024 when it will be increased to \$11,625 per month where it will remain until expiration.

In September 2014, the Company entered into an asset purchase agreement with Hy Biopharma Inc. ("Hy Biopharma") pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, the Company paid \$275,000 in cash and issued 771 shares of common stock with a fair value based on the Company's stock price on the date of grant of \$ 3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company's research and development activities and do not have alternative future use pursuant to GAAP. In March 2020, the Company issued 8,151 shares of common stock to Hy Biopharma as payment for achieving a milestone: the Company determining the Phase 3 clinical trial of HyBryte™ to be successful in the treatment of CTCL. The number of shares of common stock issued to Hy Biopharma was calculated using an effective price of \$614.40 per share, based upon a formula set forth in the purchase agreement.

Provided the sole remaining future success-oriented milestone of FDA approval is attained, the Company will be required to make an additional payment of \$5 million, if and when achieved. Such payment will be payable in restricted securities of the Company provided such number of shares does not exceed 19.9% ownership of the Company's outstanding stock. As of March 31, 2024, no other milestone or royalty payments have been paid or accrued.

As a result of the above agreements, the Company has the following contractual obligations:

Year	Research and Development	Property and Other Leases	Total
April 1 through December 31, 2024	\$ 46,000	\$ 102,817	\$ 148,817
2025	46,000	116,250	162,250
2026	46,000	—	46,000
2027	46,000	—	46,000
2028	46,000	—	46,000
Total	<u>\$ 230,000</u>	<u>\$ 219,067</u>	<u>\$ 449,067</u>

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. A liability is only recorded if management determines that it is both probable and reasonably estimable.

Note 7. Operating Segments

The Company maintains two active operating segments: Specialized BioTherapeutics and Public Health Solutions. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

	Three Months Ended March 31,	
	2024	2023
Revenues		
Specialized BioTherapeutics	\$ 117,029	\$ 155,365
Public Health Solutions	—	101,813
Total	<u>\$ 117,029</u>	<u>\$ 257,178</u>
Income (loss) from Operations		
Specialized BioTherapeutics	\$ (860,604)	\$ (910,377)
Public Health Solutions	(45,997)	427
Corporate	(1,210,490)	(1,240,739)
Total	<u>\$ (2,117,091)</u>	<u>\$ (2,150,689)</u>
Amortization and Depreciation Expense		
Specialized BioTherapeutics	\$ 953	\$ 1,071
Public Health Solutions	159	178
Corporate	476	536
Total	<u>\$ 1,588</u>	<u>\$ 1,785</u>
Other (Expense) Income, Net		
Specialized BioTherapeutics	\$ 7,540	\$ 6,082
Corporate	194,224	(62,699)
Total	<u>\$ 201,764</u>	<u>\$ (56,617)</u>
Share-Based Compensation		
Specialized BioTherapeutics	\$ 20,672	\$ 27,427
Public Health Solutions	588	994
Corporate	38,701	45,213
Total	<u>\$ 59,961</u>	<u>\$ 73,634</u>
	As of March 31, 2024	As of December 31, 2023
Identifiable Assets		
Specialized BioTherapeutics	\$ 301,709	\$ 272,099
Public Health Solutions	120,475	3,976
Corporate	7,636,201	9,521,251
Total	<u>\$ 8,058,385</u>	<u>\$ 9,797,326</u>

Note 8. Subsequent Events

Pontifax Conversion of Convertible Debt

On April 15, 2024, Pontifax delivered a conversion notice to the Company electing to convert a portion of the remaining principal balance into shares of the Company's common stock. Upon conversion, the Company issued 27,651 shares of the Company's common stock at \$5.60 per share, reducing the remaining principal balance by \$ 154,840. Pontifax may elect to convert the remaining outstanding loan drawn under the first tranche into additional shares of the Company's common stock at any time prior to repayment. The Company also has the ability to force the conversion of the loan into shares of its common stock, subject to certain conditions.

\$4.75 million Public Offering

On April 22, 2024, the Company completed a public offering of (i) 204,694 shares of the Company's common stock, (ii) pre-funded warrants to purchase 537,500 shares of the Company's common stock and (iii) common warrants to purchase 742,194 shares of the Company's common stock. The shares of common stock, or pre-funded warrants in lieu thereof, and the common warrants, were sold in units, with each unit consisting of one share of common stock or one pre-funded warrant in lieu thereof and one common warrant. Each unit comprised of common stock and common warrants was sold at a per unit price of \$6.40. Each unit comprised of pre-funded warrants and common warrants was sold at a per unit price of \$6.38, which represents the same per unit price less the \$ 0.02 per share exercise price of the pre-funded warrants. The common warrants are exercisable at a price of \$6.40 per share, are exercisable immediately and expire five years from the issuance date. The total gross proceeds to the Company from this offering were approximately \$4.75 million before deducting commissions and other estimated offering expenses payable by the Company (\$ 4.3 million, net).

Note 9. Reverse Stock Split

On June 5, 2024, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-sixteen, whereby every sixteen shares of the Company's issued and outstanding common stock was automatically combined into one issued and outstanding share of common stock without any change in the par value per share. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. The Company's common stock began trading on The NASDAQ Capital Market on a reverse split basis at the market opening on June 5, 2024. All share and per share data have been restated to reflect this reverse stock split.

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets
As of December 31, 2023 and 2022

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,446,158	\$ 13,359,615
Contracts and grants receivable	—	115,130
Unbilled revenue	171,254	—
Research and development incentives receivable, current	23,894	104,198
Prepaid expenses and other current assets	866,014	274,209
Total current assets	9,507,320	13,853,152
Security deposit	22,777	22,777
Office furniture and equipment, net of accumulated depreciation of \$121,320 and \$114,766	11,927	18,481
Deferred issuance cost	—	20,206
Right-of-use lease assets	229,834	340,987
Research and development incentives receivable, net of current portion	25,468	24,114
Total assets	\$ 9,797,326	\$ 14,279,717
Liabilities, mezzanine equity and shareholders' equity/(deficit)		
Current liabilities:		
Accounts payable	\$ 1,111,226	\$ 3,865,796
Accrued expenses	2,418,002	2,307,746
Accrued compensation	251,115	336,692
Lease liabilities, current	121,765	108,948
Convertible debt, net of debt discount of \$0 and \$102,309	2,250,000	9,897,691
Total current liabilities	6,152,108	16,516,873
Non-current liabilities:		
Convertible debt	1,010,934	—
Lease liabilities, net of current portion	111,862	233,627
Total liabilities	7,274,904	16,750,500
Commitments and contingencies (Note 10)		
Mezzanine equity:		
Series D preferred stock, \$.001 par value; 0 and 50,000 shares authorized, none issued or outstanding as of December 31, 2023 and December 31, 2022, respectively	—	43
Shareholders' equity/(deficit):		
Preferred stock, 350,000 and 300,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; none issued or outstanding	—	—
Common stock, \$.001 par value; 75,000,000 shares authorized; 648,761 and 181,898 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively ⁽¹⁾	649	182
Additional paid-in capital ⁽¹⁾	228,203,706	217,067,691
Accumulated other comprehensive income	22,243	24,747
Accumulated deficit	(225,704,176)	(219,563,446)
Total shareholders' equity/(deficit)	2,522,422	(2,470,826)
Total liabilities, mezzanine equity and shareholders' equity/(deficit)	\$ 9,797,326	\$ 14,279,717

⁽¹⁾ Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Years Ended December 31, 2023 and 2022

	Year Ended December 31,	
	2023	2022
Revenues:		
Licensing revenue	\$ —	\$ 250,000
Grant revenue	839,359	698,911
Total revenues	839,359	948,911
Cost of revenues	(742,048)	(550,822)
Gross profit	97,311	398,089
Operating expenses:		
Research and development	3,312,699	7,944,089
General and administrative	4,482,552	6,692,904
Total operating expenses	7,795,251	14,636,993
Loss from operations	(7,697,940)	(14,238,904)
Other income (expense):		
Foreign currency transaction gain (loss)	1,483	(30,549)
Interest income (expense), net	(49,129)	(822,611)
Research and development incentives	23,784	132,869
CARES Act Employee Retention Credit	120,771	—
Other income	43,223	5,921
Loss on extinguishment of debt	(393,791)	—
Change in fair value of convertible debt	43,066	—
Total other income (expense)	(210,593)	(714,370)
Net loss before income taxes	(7,908,533)	(14,953,274)
Income tax benefit	1,767,803	1,154,935
Net loss applicable to common stockholders	\$ (6,140,730)	\$ (13,798,339)
Basic and diluted net loss per share ⁽¹⁾	\$ (12.66)	\$ (76.84)
Basic and diluted weighted average common shares outstanding ⁽¹⁾	484,995	179,565

⁽¹⁾ Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2023 and 2022

	Year Ended December 31,	
	2023	2022
Net loss	\$ (6,140,730)	\$ (13,798,339)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(2,504)	(17,195)
Comprehensive loss	<u>\$ (6,143,234)</u>	<u>\$ (13,815,534)</u>

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Mezzanine Equity and Shareholders' Equity (Deficit)
For the Years Ended December 31, 2023 and 2022

	Mezzanine Equity- Series D Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2021	—	\$ —	178,744	\$ 179	\$ 216,445,584	\$ 41,942	\$ (205,765,107)	\$ 10,722,598
Issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement			539	1	79,353	—	—	79,354
Issuance costs associated with B. Riley At Market Issuance Sales Agreement			—	—	(2,593)	—	—	(2,593)
Declaration of Series D preferred stock for stock dividend	—	43	—	—	(43)	—	—	(43)
Fractional shares issued in reverse stock split			1,222	1	(1)	—	—	—
Issuance of common stock to vendors			1,393	1	212,002	—	—	212,003
Share-based compensation expense			—	—	333,389	—	—	333,389
Foreign currency translation adjustment			—	—	—	(17,195)	—	(17,195)
Net loss			—	—	—	—	(13,798,339)	(13,798,339)
Balance, December 31, 2022	—	\$ 43	181,898	\$ 182	\$ 217,067,691	\$ 24,747	\$ (219,563,446)	\$ (2,470,826)
Issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement			53,202	53	3,091,409	—	—	3,091,462
Issuance costs associated with B. Riley At Market Issuance Sales Agreement			—	—	(113,217)	—	—	(113,217)
Redemption of Series D preferred stock	—	(43)	—	—	—	—	—	—
Issuance of common stock and pre-funded warrants in connection with May 2023 public offering			143,844	144	8,495,673	—	—	8,495,817
Issuance costs associated with May 2023 public offering			—	—	(834,061)	—	—	(834,061)
Issuance of common stock to vendors			3,125	3	72,997	—	—	73,000
Issuance of common stock upon exercise of pre-funded warrants			264,714	265	3,034	—	—	3,299
Issuance of common stock for unexercised purchase option			1,978	2	49,998	—	—	50,000
Share-based compensation expense			—	—	370,182	—	—	370,182
Foreign currency translation adjustment			—	—	—	(2,504)	—	(2,504)
Net loss			—	—	—	—	(6,140,730)	(6,140,730)
Balance, December 31, 2023	—	\$ —	648,761	\$ 649	\$ 228,203,706	\$ 22,243	\$ (225,704,176)	\$ 2,522,422

Adjusted to reflect the reverse stock split of one-for- sixteen effective June 5, 2024

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2023 and 2022

	2023	2022
Operating activities:		
Net loss	\$ (6,140,730)	\$ (13,798,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	6,554	24,562
Non-cash lease expense	111,153	112,714
Share-based compensation	370,182	333,389
Issuance of common stock to vendors for services	73,000	212,003
Issuance of common stock for unexercised purchase option	50,000	—
Loss on extinguishment of debt	393,791	—
Change in fair value of convertible debt	(43,066)	—
Amortization of deferred issuance costs associated with convertible debt	12,518	41,538
Change in operating assets and liabilities:		
Licensing, contracts and grants receivable	(56,124)	23,759
Prepaid expenses and other current assets	(591,805)	8,694
Research and development incentives receivable	90,016	73,374
Operating lease liability	(108,948)	(111,122)
Accounts payable and accrued expenses	(2,685,073)	396,651
Accrued compensation	(85,577)	33,756
Net cash used in operating activities	(8,604,109)	(12,649,021)
Investing activities:		
Purchases of office furniture and equipment	—	(13,073)
Net cash used in investing activities	—	(13,073)
Financing activities:		
Proceeds from issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement	3,091,462	79,354
Costs associated with B. Riley At Market Issuance Sales Agreement	(93,011)	(2,533)
Proceeds from issuance of common stock and pre-funded warrants pursuant to public offering	8,495,817	—
Stock issuance costs associated with public offering	(834,061)	—
Proceeds from the exercise of pre-funded warrants	3,299	—
Convertible debt repayments	(7,000,000)	—
Net cash provided by financing activities	3,663,506	76,821
Effect of exchange rate on cash and cash equivalents	27,146	(99,009)
Net decrease in cash and cash equivalents	(4,913,457)	(12,684,282)
Cash and cash equivalents at beginning of year	13,359,615	26,043,897
Cash and cash equivalents at end of year	\$ 8,446,158	\$ 13,359,615
Supplemental information:		
Cash paid for state income taxes	\$ 20,730	\$ 16,043
Cash paid for interest	\$ 552,058	\$ 857,411
Cash paid for lease liabilities:		
Operating lease	\$ 133,817	\$ 133,300
Non-cash investing and financing activities:		
Right-of-use assets and lease liabilities recorded	\$ —	\$ 347,546
Deferred issuance cost reclassified to additional paid-in capital	\$ 20,208	\$ 60
Declaration of Series D preferred stock for stock dividend	\$ —	\$ 43
Redemption of Series D preferred stock for stock dividend	\$ 43	\$ —

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

Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company”) is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: Specialized BioTherapeutics and Public Health Solutions.

The Company's Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin sodium), a novel photodynamic therapy (“PDT”) utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma (“CTCL”). With successful completion of the Phase 3 FLASH (Fluorescent Light And Synthetic Hypericin) study, regulatory approval is being pursued in the United States (“U.S.”) and Europe. Following submission of a new drug application (“NDA”) for HyBryte™ in the treatment of CTCL in December 2022, the Company received a refusal to file (“RTF”) letter from the U.S. Food and Drug Administration (“FDA”) in February 2023. In April 2023, the Company had a Type A meeting with the FDA to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards U.S. marketing approval and commercialization. In order to accept an NDA filing for HyBryte™, the FDA is requiring positive results from a second, Phase 3 pivotal study in addition to the Phase 3, randomized, double-blind, placebo-controlled FLASH study previously conducted in this orphan indication. Based on this feedback, the Company is collaboratively engaging in active discussions with both the FDA and the European Medicines Agency (“EMA”) in order to define the protocol and evaluate the feasibility of conducting the additional Phase 3 clinical trial evaluating HyBryte™ in the treatment of CTCL in support of potential marketing approval.

Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, the Company's first-in-class Innate Defense Regulator (“IDR”) technology, and dusquetide (SGX942 and SGX945) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer and aphthous ulcers in Behçet's Disease.

The Company's Public Health Solutions business segment includes development programs for RiVax®, its ricin toxin vaccine candidate and SGX943, its therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs, including a program targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of the vaccine programs incorporates the use of the Company's proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (“NIAID”), the Biomedical Advanced Research and Development Authority and the Defense Threat Reduction Agency.

The Company primarily generates revenues under government grants and contracts principally from the National Institutes of Health (“NIH”). The Company was awarded a subcontract that originally provided for approximately \$1.5 million from a NIAID grant over two years for development of CiVax™ and a subcontract that originally provided for approximately \$ 1.1 million from a FDA Orphan Products Development grant over four years for an expanded study of HyBryte™ in the treatment of CTCL. The Company will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the FDA regulations, and other regulatory authorities, litigation, and product liability.

Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of

December 31, 2023, the Company had an accumulated deficit of \$ 225,704,176 and working capital of \$ 3,355,212. During the year ended December 31, 2023, the Company incurred a net loss of \$6,140,730 and used \$8,604,109 of cash in operating activities. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be determined largely by the budgeted operational expenditures incurred in regards to the progression of its product candidates. Management believes that the Company has sufficient resources available to support its development activities and business operations and timely satisfy its obligations as they become due into the fourth quarter of 2024. The Company does not have sufficient cash and cash equivalents as of the date of filing this Annual Report on Form 10-K to support its operations for at least the 12 months following the date the financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern through 12 months after the date the financial statements are issued.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, the Company plans to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of the common stock via an At Market Issuance Sales Agreement and potentially amending the loan agreement with Pontifax to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce the Company's debt repayments; however, none of these alternatives are committed at this time. There can be no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to it to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that it will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, the Company will not have sufficient cash resources and liquidity to fund its business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms when needed may require the Company to delay, limit, or eliminate the development of business opportunities and its ability to achieve its business objectives and its competitiveness, and its business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce the Company's ability to access capital, which could negatively affect its liquidity and ability to continue as a going concern. In addition, the perception that the Company may not be able to continue as a going concern may cause others to choose not to deal with it due to concerns about its ability to meet its contractual obligations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of December 31, 2023, the Company had cash and cash equivalents of \$ 8,446,158 as compared to \$13,359,615 as of December 31, 2022, representing a decrease of \$4,913,457 or 37%. As of December 31, 2023, the Company had working capital of \$3,355,212 as compared to a working capital deficit of (\$ 2,663,721) as of December 31, 2022, representing an increase of \$ 6,018,933 or 226%. The decrease in cash and cash equivalents was primarily related to cash used in operating activities. The increase in working capital is primarily the result of the net proceeds received from financing activities partially offset by the immediate paydown of \$5 million of outstanding debt principal balance and any accrued interest resulting from the amendment to the convertible debt financing agreement with Pontifax during the year ended December 31, 2023.

Management's business strategy can be outlined as follows:

- Following positive primary endpoint results for the Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) clinical trial of HyBryte™ in CTCL as well as further statistically significant improvement in response rates with longer treatment (18 weeks compared to 12 and 6 weeks of treatment), collaboratively engage in discussions with both the FDA and the EMA in order to define the protocol and evaluate the feasibility of conducting a second clinical study in order to advance HyBryte™ towards U.S. marketing approval and commercialization while continuing to explore potential marketing approval and partnership in Europe.
- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.

- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 (dusquetide) in the treatment in oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.
- Expanding development of dusquetide under the research name SGX945 into Beh çet's Disease with the conduct of a Phase 2a clinical trial, where previous studies with dusquetide in oral mucositis have validated the biologic activity in aphthous ulcers induced by chemotherapy and radiation.
- Continue development of the Company's heat stabilization platform technology, ThermoVax[®], in combination with its programs for RiVax[®] (ricin toxin vaccine), and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses and multivalent combinations), with U.S. government or non-governmental organization funding support.
- Continue to apply for and secure additional government funding for the Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.
- Pursue business development opportunities for pipeline programs, as well as explore all strategic alternatives, including but not limited to merger/acquisition strategies.
- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

The Company's plans with respect to its liquidity management include, but are not limited to, the following:

- The Company has up to approximately \$844,000 in active government grant funding still available as of December 31, 2023 to support its associated research programs through May 2026, provided the federal agencies do not elect to terminate the grants for convenience. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies. However, there can be no assurance that the Company will obtain additional governmental grant funding.
- The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.
- The Company will continue to pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program if the program is available.
- The Company plans to pursue potential partnerships for pipeline programs as well as continue to explore merger and acquisition strategies. However, there can be no assurances that the Company can consummate such transactions.
- The Company completed a public offering of 143,844 shares of its common stock, pre-funded warrants to purchase 264,813 shares of its common stock and common warrants to purchase up to 408,656 shares of its common stock at a combined public offering price of \$20.80. The pre-funded warrants had an exercise price of \$0.001. The common warrants have an exercise price of \$24.00 per share, are exercisable immediately and expire five years from the issuance date. The total gross proceeds to the Company from this offering was approximately \$8.5 million before deducting commissions and other estimated offering expenses. The Company plans to use the proceeds for further support of its programs, as well as for working capital; and
- The Company is currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that it can consummate such a transaction, or consummate a transaction at favorable pricing.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision-making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: Specialized BioTherapeutics and Public Health Solutions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments – Credit Losses (Topic 326)* and subsequently related amendments (ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11, and ASU 2022-02). This guidance replaces the existing incurred loss impairment guidance and establishes a single allowance framework for financial assets carried at amortized cost based on expected credit losses. The estimate of expected credit losses requires the incorporation of historical information, current conditions, and reasonable and supportable forecasts. The Company adopted this new accounting standard effective January 1, 2023 and all of the related amendments using the retrospective method. The Company determined there was no effect to its opening balance of shareholders' equity of initially applying the new credit loss standard to its contracts and grants receivable. There was no significant impact to the Company's operating results for the current period due to this standard update. Management has evaluated the adoption of ASC Topic 326 and concluded the effect of the adoption was immaterial to the financial statements as a whole.

Contracts and grants receivable consist of amounts due from various grants from the NIH and contracts from NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for credit losses has been established. If amounts become uncollectible, they are charged to operations.

Impairment of Long-Lived Assets

Office furniture and equipment, right of use assets and website development costs with finite lives are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the years ended December 31, 2023 and 2022.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available

to the Company on December 31, 2023 and 2022. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
- Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, contracts and grants receivable, research and development incentives receivable, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

The carrying amount reported in the consolidated balance sheet as of December 31, 2023 for the convertible debt is its fair value – see Note 5. The principal amount of the convertible debt was \$3,000,000 at December 31, 2023 and the fair value was approximately \$3,260,934. The fair value of the debt was estimated using the Monte Carlo valuation method, which utilizes certain unobservable inputs. As a result, the fair value estimate represents a Level 3 measurement.

A roll forward of the carrying value of the convertible debt to December 31, 2023 is as follows:

	Balance December 31, 2022	Issued	Adjustment to fair value	Balance December 31, 2023
Convertible debt at fair value	\$ —	\$ 3,304,000	\$ (43,066)	\$ 3,260,934

Deferred Issuance Costs

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

Revenue Recognition

The Company's revenues include revenues generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

The Company also records revenue from contracts with customers in accordance with Accounting Standards Codification Topic 606 ("ASC 606"), *Revenue From Contracts with Customers*. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Certain amounts received from or billed to customers in accordance with contract terms are deferred and recognized as future performance obligations are satisfied. All amounts earned under contracts with customers other than sales-based royalties are classified as licensing revenue. Sales-based royalties under the Company's license agreements would be recognized as royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed under the Company's 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, restricted stock, deferred stock and unrestricted stock to the Company's employees and non-employees (including consultants). The shares issued under the 2015 Plan are registered on Form S-8 (SEC File No. 333-208515). However, as shares of common stock are not covered by a reoffer prospectus, the certificates reflecting

such shares reflect a Securities Act of 1933, as amended restrictive legend. Stock compensation expense for equity-classified awards to non-employees is measured on the date of grant and is recognized when the services are performed.

The fair value of options issued during the years ended December 31, 2023 and 2022 was estimated using the Black-Scholes option-pricing model and the following assumptions:

- a dividend yield of 0%;
- an expected life of four years;
- volatility of 94% - 110% for 2023 and 84% - 87% for 2022; and
- risk-free interest rates ranging from 3.48% to 4.35% in 2023 and ranging from 1.12% to 4.51% in 2022.

The fair value of each option grant made during 2023 and 2022 was estimated on the date of each grant and recognized as share-based compensation expense ratably over the option vesting periods, which approximates the service period. The expected term of options granted is derived using company history of options exercised. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The Company accounts for forfeitures as they are incurred.

Foreign Currency Transactions and Translation

In 2018, the Company changed the status of a wholly-owned subsidiary in the UK from inactive to active and incurred expenditures in multiple currencies including the U.S. dollar, the British Pound and the Euro to fund its clinical trial operations in the UK and select countries in Europe. In accordance with FASB ASC 830 *Foreign Currency Matters*, the UK subsidiary expresses its U.S. dollar and Euro denominated transactions in its functional currency, the British Pound, with related transaction gains or losses included in net loss. On a quarterly basis, the financial statements of the UK subsidiary are translated into U.S. dollars and consolidated into the Company's financials, with related translation adjustments reported as a cumulative translation adjustment ("CTA"), which is a component of accumulated other comprehensive loss. In 2023 and 2022, the Company recognized a foreign currency transaction gain of \$1,483 and a foreign currency transaction loss of (\$ 30,549), respectively, in the accompanying consolidated statements of operations.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company sold 2022, 2021 and 2020 New Jersey NOL carryforwards resulting in the recognition of income tax benefits, net of transaction costs of \$1,767,803 and \$1,154,935 during the years ended December 31, 2023 and 2022, respectively. The Company sold its 2022 New Jersey NOLs and has recorded a receivable of \$606,606 which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheet for the year ended December 31, 2023. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2023 and 2022. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2023 or 2022.

Research and Development Incentive Income and Receivable

The Company recognizes other income from UK research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The small or medium sized enterprise ("SME") research and development tax relief program supports companies that seek to research and develop an advance in their field and is governed through legislative law by HM Revenue & Customs as long as specific eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the SME research and development tax relief program described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. As the tax incentives may be received without regard to an entity's actual tax liability, they are not subject to accounting for income taxes. As a result, amounts realized under the SME research and development tax relief program are recorded as a component of other income.

The research and development incentive receivable represents an amount due in connection with the above-described tax relief program. The Company has recorded a research and development incentive receivable of approximately \$49,000 and \$128,000 as of December 31, 2023 and 2022, respectively in the consolidated balance sheets.

The following table shows the change in the UK research and development incentives receivable from December 31, 2022 to December 31, 2023:

	Current	Long-Term	Total
Balance at December 31, 2022	\$ 104,198	\$ 24,114	\$ 128,312
UK research and development incentives, transfer	24,114	(24,114)	—
UK research and development incentives	—	24,897	24,897
Adjustments to 2021 and 2022 incentives earned	(1,113)	—	(1,113)
UK research and development incentives cash receipt	(104,422)	—	(104,422)
Foreign currency translation	1,117	571	1,688
Balance at December 31, 2023	<u>\$ 23,894</u>	<u>\$ 25,468</u>	<u>\$ 49,362</u>

Loss Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Included within the Company's weighted average common shares outstanding for the year ended December 31, 2023, are common shares issuable upon the exercise of the pre-funded warrants associated with the May 2023 public offering, as these pre-funded warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

The following table summarizes potentially dilutive adjustments to the number of common shares which were excluded from the diluted calculation because their effect would be anti-dilutive due to the losses in each period:

	December 31, 2023	December 31, 2022
Common stock purchase warrants	408,640	42
Stock options	56,609	11,946
Convertible debt	273,973	30,865
Total	<u>739,222</u>	<u>42,853</u>

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and stock options and to accrue for clinical trials in process that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Note 3. Leases

The Company classifies a lease for its office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey as an operating lease, and recorded a related right-of-use lease asset and lease liability accordingly. Pursuant to an amendment executed on June 21, 2022, the lease has been extended to October 2025. The current rent of \$11,367 per month will be maintained until November 2024 when it will be increased to \$11,625 where it will remain until expiration. As of December 31, 2023 and 2022, the Company's consolidated balance sheets included a right-of-use lease asset of \$229,834 and \$340,987 for the office space, respectively. The Company's consolidated balance sheets as of December 31, 2023 and 2022 included corresponding lease liabilities of \$233,627 and \$342,575 for the office space, respectively.

The following represents a reconciliation of contractual lease cash flows to the right-of-use lease asset and liability recognized in the financial statements:

	Operating Lease
Contractual cash payments for the remaining lease term as of December 31, 2023	
2024	\$ 136,917
2025	116,250
Less implied interest	19,540
Total	\$ 233,627
Discount rate applied	8.47 %
Remaining lease term (months) as of December 31, 2023	22
Right-of-use lease asset:	
Right-of-use lease asset, January 1, 2022	\$ 106,155
New lease extension June 21, 2022	347,546
Less: reduction/amortization	112,714
Right-of-use lease asset, December 31, 2022	340,987
Less: reduction/amortization	111,153
Right-of-use lease asset, December 31, 2023	\$ 229,834
Lease liability:	
Lease liability, January 1, 2022	\$ 106,151
New lease extension June 21, 2022	347,546
Less: repayments	111,122
Lease liability, December 31, 2022	342,575
Less: repayments	108,948
Lease liability, December 31, 2023	\$ 233,627
Lease expense for the year ended December 31, 2022:	
Lease expense	\$ 134,892
Total	\$ 134,892
Lease expense for the year ended December 31, 2023:	
Lease expense	\$ 136,022
Total	\$ 136,022

Note 4. Accrued Expenses

The following is a summary of the Company's accrued expenses:

	December 31,	
	2023	2022
Clinical trial expenses	\$ 1,993,784	\$ 1,884,117
Other	424,218	423,629
Total	\$ 2,418,002	\$ 2,307,746

Note 5. Debt

In December 2020, the Company entered into a \$20 million convertible debt financing agreement with Pontifax Medison Debt Financing ("Pontifax"), the healthcare-dedicated venture and debt fund of the Pontifax life science funds. Under the terms of the agreement with Pontifax, the Company had access to up to \$20 million in convertible debt financing in three tranches, which will mature on June 15, 2025 and had an interest-only period for the first two years with a fixed interest rate of 8.47% on borrowed amounts and an interest rate of 1% on amounts available but not borrowed as an unused line of credit fee. After the interest-only period, the outstanding principal is to be repaid in quarterly payments of \$1 million each commencing in the first quarter of 2023. The agreement is secured by a lien covering substantially all of the Company's assets, other than intellectual property.

Upon the closing of this transaction, the Company accessed the first tranche of \$10 million, had the option to draw the second tranche of \$5 million at any time during the initial 12 months of the loan and the third tranche of \$5 million upon filing of the HyBryte™ NDA, subject to certain conditions. The Company elected to let the options to borrow both the second and third tranches expire as of December 15, 2021 and March 15, 2022, respectively.

On April 19, 2023, the Company entered into an amendment to the convertible debt financing agreement dated December 15, 2020 with Pontifax. The amendment called for the immediate payment of \$5 million of the outstanding principal balance and any accrued interest, waived any prepayment charge in connection with the repayment of this amount and resulted in an outstanding principal balance of \$3 million. The amendment also provided for a new interest only period from the date of the amendment through June 30, 2024, reduced quarterly principal repayments from \$1 million to \$750,000 and eliminated the minimum cash covenant. Further, the amendment reduced the conversion price with respect to the remaining principal amount under the agreement to (i) 90% of the closing price of the Company's common stock on the day before the delivery of the conversion notice with respect to the first 36,790 shares of the Company's common stock issuable upon conversion and to (ii) \$27.20 with respect to all shares of the Company's common stock issuable upon conversion in excess of the first 36,790 shares so issued. The remaining terms of the agreement remain in effect without modification.

The amendment to the convertible debt financing agreement with Pontifax resulted in the extinguishment of the original convertible debt for accounting purposes. The Company concluded that the amended debt instrument has an embedded derivative that requires bifurcation pursuant to ASC 815-15-25-1 and qualifies for the fair value option in accordance with ASC 815-15-25-4 through ASC 815-15-25-6. The Company elected to account for the amended convertible debt using the fair value option, which requires the Company to record changes in fair value as a component of other income or expense. The fair value of the convertible debt on the date of the amendment was approximately \$3,304,000, which resulted in the recognition of a loss on extinguishment of approximately \$394,000 on the Company's accompanying consolidated statements of operations for the year ended December 31, 2023. The fair value of the convertible debt as of December 31, 2023 was approximately \$3,260,934, which resulted in the recognition of \$43,066 of other income from the change in the fair value of the convertible debt on the Company's accompanying consolidated statements of operations for the year ended December 31, 2023. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

Assumptions	4/19/2023	9/30/2023	12/31/2023
Stock price	\$ 1.72	\$ 0.56	\$ 0.76
Volatility	75.20%	110.50%	141.90%
Discount rate	16.28%	14.84%	13.62%
Risk-free rate	4.27%	5.24%	4.65%

Interest expense incurred during the years ended December 31, 2023 and 2022 was \$ 402,615 and \$847,000, respectively. Interest expense paid during the years ended December 31, 2023 and 2022 was \$552,058 and \$857,411, respectively.

Pontifax may elect to convert the outstanding loan drawn into shares of the Company's common stock at any time prior to repayment. There was \$3,000,000 of principal and \$63,351 of accrued interest outstanding as of December 31, 2023. The Convertible Notes were convertible at (i) 90% of the closing price of our common stock on the day before the delivery of the conversion notice with respect to the first 36,790 shares issuable upon conversion as of December 31, 2023 and (ii) \$ 27.20 with respect to all shares issuable upon conversion in excess of the first 36,790 shares issued upon conversion as of December 31, 2023. The Company also has the ability to force the conversion of the loan into shares of the Company's common stock at the same conversion price, subject to certain conditions.

Annual principal and interest payments due, according to the agreement's contractual terms, assuming no conversion is as follows:

Year	Principal	Interest	Total
2024	\$ 2,250,000	\$ 270,808	\$ 2,520,808
2025	750,000	16,012	766,012
Total	\$ 3,000,000	\$ 286,820	\$ 3,286,820

Note 6. Income Taxes

The income tax benefit consisted of the following for the years ended December 31, 2023 and 2022:

	2023	2022
Federal	\$ —	\$ —
Foreign	—	—
State & Local	(1,767,803)	(1,154,935)
Income tax benefit	<u>\$ (1,767,803)</u>	<u>\$ (1,154,935)</u>

The significant components of the Company's deferred tax assets and liabilities at December 31, 2023 and 2022 are as follows:

	2023	2022
Net operating loss carry forwards	\$ 27,522,000	\$ 27,252,000
Orphan drug and research and development credit carry forwards	8,921,000	8,837,000
Equity based compensation	246,000	285,000
Intangibles	1,409,000	1,696,000
Capitalized research and development (Section 174)	2,311,000	1,832,000
Lease liability	66,000	96,000
Other	(12,000)	—
Total	40,463,000	39,998,000
Valuation allowance	<u>(40,398,000)</u>	<u>(39,902,000)</u>
Net deferred tax assets	65,000	96,000
Right of use asset	<u>(65,000)</u>	<u>(96,000)</u>
Total gross deferred tax liabilities	(65,000)	(96,000)
Net deferred tax assets	\$ —	\$ —

The Company had gross NOLs at December 31, 2023 of approximately \$ 123.0 million for federal tax purposes, approximately \$ 12.9 million for state tax purposes and approximately \$3.7 million for foreign tax purposes. Federal losses generated in 2018 or later will carry forward indefinitely. In addition, the Company has approximately \$8.9 million of various tax credits which credit the Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. federal jurisdiction, and various state and local jurisdictions. During the years ended December 31, 2023 and 2022 in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carryforwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of \$1,767,803 and \$1,154,935, respectively, of income tax benefit, net of transaction costs. The Company sold its 2022 New Jersey NOLs and has recorded a receivable of \$606,606 which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheet for the year ended December 31, 2023. There can be no assurance as to the continuation or magnitude of this program in the future.

The Tax Cuts and Jobs Act of 2017 ("TCJA") has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company must now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Therefore, the capitalization of research and development costs in accordance with IRC 174 resulted in a deferred tax asset of \$2,310,677.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2023 and 2022 were as follows:

	2023	2022
Federal tax at statutory rate	(21.0)%	(21.0)%
State tax benefits, plus sale of NJ NOL, net of federal benefit	(21.6)	(2.4)
Foreign tax rate difference	0.1	0.2
Orphan drug and research and development credits	(2.0)	(3.9)
Permanent differences	0.9	3.1
Foreign NOL adjustments	0.7	0.4
Expiration of tax attributes	14.2	9.1
Change in valuation allowance	6.3	6.8
Income tax benefit	<u>(22.4)%</u>	<u>(7.7)%</u>

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, 2023, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception and as such, tax years subject to potential tax examination could apply from 2011, the earliest year with a net operating loss carryover, 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 years ended December 31, 2023 and 2022.

Note 7. Shareholders' Equity (Deficit)

Preferred Stock

The Company has 350,000 shares of preferred stock authorized, of which 50,000 were designated as Series D preferred stock during the year ended December 31, 2023.

Series D Preferred Stock

On December 21, 2022, the Board of Directors of the Company declared a dividend for the stockholders of record on January 3, 2023. The dividend consists of one one-thousandth of a share of Series D preferred stock, par value \$ 0.001 per share, for each outstanding share of the Company's common stock. The Series D preferred stock has the following rights and restrictions:

General; Transferability - Series D preferred stock shares will be in book-entry form without certificates. Transfers can only happen alongside common stock transfers, with 1/1,000th of a Series D preferred stock share transferred for each common stock share transferred.

Voting Rights - Each Series D preferred stock share gives the holder 1,000,000 votes. If a shareholder owns a fraction of a share, they will have a proportional number of votes.

Series D preferred stock and common stock shares only vote together on two specific matters:

1. Any plan to change the Company's Certificate of Incorporation for a reverse stock split.
 2. Any plan to delay a stockholders' meeting to vote on a reverse stock split (the "Adjournment Proposal").
- When voting on the reverse stock split or the Adjournment Proposal, each Series D preferred stock share (or fraction of a share) will vote the same way as the common stock share it was issued from.

Dividend Rights - The holders of Series D preferred stock will not be entitled to receive dividends of any kind.

Liquidation Preference - If the Company undergoes liquidation, dissolution, or winding up, Series D preferred stock has priority over common stock for asset distribution. In such a situation, Series D preferred stockholders will receive a cash payment of \$0.001 per share before any distribution is made to common stockholders.

Redemption - If Series D preferred stockholders do not attend or vote by proxy at a meeting for the reverse stock split and Adjournment Proposal, their shares will be automatically redeemed by the Company. If any Series D preferred stock remains after this redemption, it can be redeemed in one of two ways:

1. The Board decides to redeem the shares at a time and date of their choosing.
2. The shares will be automatically redeemed when the Company's stockholders approve the reverse stock split during a meeting for this purpose.

When Series D preferred stock is redeemed, stockholders receive a cash payment based on the number of shares they own. For every 100 whole shares redeemed, the stockholder will get \$ 0.10 in cash.

The Series D preferred stock shares were classified as mezzanine equity as of December 31, 2022 since they were not mandatorily redeemable but were redeemable based on an event not entirely controlled by the Company. All Series D preferred stock were redeemed in conjunction with the special meeting of the shareholders' on February 8, 2023.

Common Stock

The following items represent transactions in the Company's common stock for the year ended December 31, 2023:

- The Company issued a vendor 3,125 shares of fully vested common stock with a fair value based on a closing price of \$23.36 per share on April 27, 2023, the date of issuance.
- The Company sold 53,202 shares of common stock pursuant to the At Market Issuance Sales Agreement ("B. Riley Sales Agreement") with B. Riley Securities, Inc. ("B. Riley") at a weighted average price of \$58.08 per share.
- The Company issued 1,978 shares of fully vested common stock pursuant to an exclusive option agreement at \$25.28 per share on May 2, 2023. The share price was calculated using the average closing price of the common stock for the ten days immediately preceding April 27, 2023, the effective date of the option agreement.
- The Company sold 143,844 shares of common stock and 264,813 pre-funded warrants pursuant to the May 2023 public offering for \$20.80 per share on May 9, 2023.
- The Company issued 126,438 shares of common stock pursuant to the exercise of pre-funded warrants associated with the May 2023 public offering with an exercise price of \$0.02 on May 9, 2023.
- The Company issued 58,625 shares of common stock pursuant to the exercise of pre-funded warrants associated with the May 2023 public offering with an exercise price of \$0.02 on May 10, 2023.
- The Company issued 21,125 shares of common stock pursuant to the exercise of pre-funded warrants associated with the May 2023 public offering with an exercise price of \$0.02 on May 22, 2023.

- The Company issued 25,001 shares of common stock pursuant to the cashless exercise of pre-funded warrants associated with the May 2023 public offering with an exercise price of \$0.02 on June 8, 2023.
- The Company issued 33,525 shares of common stock pursuant to the cashless exercise of pre-funded warrants associated with the May 2023 public offering with an exercise price of \$0.02 on September 6, 2023.

The following items represent transactions in the Company's common stock for the year ended December 31, 2022:

- The Company issued a vendor 337 shares of fully vested common stock with a fair value of \$148.80 per share on February 7, 2022.
- The Company issued a vendor 401 shares of fully vested common stock with a fair value of \$124.80 per share on May 6, 2022.
- The Company issued a vendor 229 shares of fully vested common stock with a fair value of \$218.40 per share on August 5, 2022.
- The Company issued a vendor 105 shares of fully vested common stock with a fair value of \$115.20 per share on October 4, 2022.
- The Company issued a vendor 321 shares of fully vested common stock with a fair value of \$156.00 per share on November 7, 2022.
- The Company issued 539 shares of common stock pursuant to the B. Riley Sales Agreement at a weighted average price of \$148.64 per share.

All issuances of the Company's common stock for the years ended December 31, 2023 and 2022 described above, other than shares issued to vendors or issued pursuant to the exclusive option agreement, were registered on a Registration Statement on Form S-8 (SEC File No. 333-208515), a Registration Statement on Form S-1 (333-271049) and a Registration Statement on Form S-3 (SEC File No. 333-239928). The certificates evidencing unregistered shares reflect a Securities Act of 1933, as amended, restrictive legend.

The issuances of the Company's common stock to vendors and pursuant to the exclusive option agreement as described above were exempt under Section 4(a)(2) of the Securities Act of 1933, as amended. The recipients are knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about the Company or had adequate access to information about the Company. The vendors represented to the Company that the vendors are not "consultants" for purposes of Nasdaq Listing Rule 5635(c).

B. Riley At Market Issuance Sales Agreement

On August 11, 2017, the Company entered into the B. Riley Sales Agreement to sell shares of the Company's common stock from time to time, through an "at-the-market" equity offering program under which B. Riley acts as sales agent. Under the B. Riley Sales Agreement, the Company set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales may be requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The B. Riley Sales Agreement provided that B. Riley was entitled to compensation for its services in an amount equal to 3% of the gross proceeds from the sale of shares sold under the B. Riley Sales Agreement. The B. Riley Sales Agreement has expired.

Note 8. Stock Option Plans and Warrants to Purchase Common Stock

Stock Option Plans

The Amended and Restated 2005 Equity Incentive Plan ("2005 Plan") was replaced by the 2015 Plan, which was approved in June 2015. No securities are available for future issuance under the 2005 Plan. In September 2022, the stockholders approved an amendment to the 2015 Plan to increase the maximum number of shares of common stock available for

issuance under the plan by 4,000,000 shares. As of December 31, 2023, there are 5,943,590 shares currently available for grants under the 2015 Plan. The plan is divided into four separate equity programs:

- 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock,
- 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,
- 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and
- 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

Shares available for grant under the 2015 Plan were as follows:

Shares available for grant at January 1, 2023	5,988,368
Options granted	(45,715)
Options forfeited	937
Options exercised	—
Shares available for grant at December 31, 2023	<u>5,943,590</u>

Activity under the 2005 Plan and the 2015 Plan for the years ended December 31, 2023 and 2022

	Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2021	8,719	\$ 593.92
Granted	3,497	141.61
Forfeited	(236)	1,727.66
Cancelled	(34)	187.20
Exercised	—	—
Balance outstanding at December 31, 2022	11,946	\$ 435.32
Granted	45,715	10.45
Forfeited	(1,052)	533.80
Cancelled	—	—
Exercised	—	—
Balance outstanding at December 31, 2023	<u>56,609</u>	<u>\$ 90.58</u>

As of December 31, 2023, there were 19,187 options exercisable with a weighted average exercise price of \$ 236.90 and a weighted average remaining contractual term of 7.99 years. As of December 31, 2023, there were 56,609 options outstanding with a weighted average remaining term of 9.25 years. Options outstanding as of December 31, 2023 had no intrinsic value.

The Company awarded 45,715 and 3,474 stock options during the years ended December 31, 2023 and 2022, respectively, which had a weighted average grant date fair value per share of \$8.05 and \$89.10, respectively. The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2023 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
\$9.44 - \$540.00	9.31	56,182	18,760
\$1,776.00 – 5,256.00	1.52	427	427
Total	9.25	56,609	19,187

The Company's share-based compensation expense for the years ended December 31, 2023 and 2022 was recognized as follows:

Share-based compensation	2023	2022
Research and development	\$ 150,466	\$ 142,879
General and administrative	219,716	190,510
Total	\$ 370,182	\$ 333,389

At December 31, 2023, the total compensation cost for stock options not yet recognized was approximately \$ 421,000 and will be expensed over the next three years.

Warrants to Purchase Common Stock

Warrant activity for the years ended December 31, 2023 and 2022 was as follows:

	Warrants	Weighted Average Exercise Price
Balance at December 31, 2021	13,868	\$ 540.68
Granted	—	—
Exercised	—	—
Expired	(13,826)	540.90
Balance at December 31, 2022	42	\$ 468.00
Granted	673,445	14.56
Exercised	(264,815)	0.02
Expired	(42)	468.00
Balance at December 31, 2023	408,640	\$ 24.00

The remaining life, by grant date, for outstanding warrants at December 31, 2023 was:

Grant Date	Exercise Price	Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
May 09, 2023	\$ 24.00	4.36	408,640	408,640

Note 9. Concentrations

At December 31, 2023 and 2022, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation ("SIPC") and the Federal Deposit Insurance Corporation ("FDIC"). Currently, the Company is covered up to \$250,000 by the SIPC and FDIC and at times maintains cash balances in excess of the SIPC and FDIC coverages.

Note 10. Commitments and Contingencies

The Company has commitments of approximately \$230,000 as of December 31, 2023 over the next five years for several licensing agreements with partners and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to approximately \$13.2 million, royalties on net sales of covered products ranging from 2% to 3%, sub-license income royalties on covered products up to 15% and sub-license global net sales royalties on covered products ranging from 1.5% to 2.5%, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

The Company currently leases approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey. This office space currently serves as the Company's corporate headquarters, and both of the Company's business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended from November 2022 to October 2025. The current rent is approximately \$11,367 per month and will remain so through October 2024. The rent for the lease period starting November 2024 is approximately \$11,625 per month.

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. ("Hy Biopharma") pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, the Company paid \$275,000 in cash and issued 12,328 shares of common stock with a fair value based on the Company's stock price on the date of grant of \$ 3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company's research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the U.S. In March 2020, the Company issued 130,413 fully vested shares of common stock to Hy Biopharma as payment for achieving a milestone: the Company determining the Phase 3 clinical trial of HyBryte™ to be successful in the treatment of CTCL. The number of shares of common stock issued to Hy Biopharma was calculated using an effective price of \$38.40 per share, based upon a formula set forth in the purchase agreement.

Provided the sole remaining future success-oriented milestone of FDA approval is attained, the Company will be required to make an additional payment of \$5 million, if and when achieved. Such payment will be payable in restricted securities of the Company provided such number of shares does not exceed 19.9% ownership of the Company's outstanding stock. As of December 31, 2023, no other milestone or royalty payments have been paid or accrued.

In January 2020, the Company's Board of Directors authorized the amendment of Dr. Schaber's employment agreement to increase the number of shares of the Company's common stock from 334 to 33,334 issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2024	\$ 46,000	\$ 136,917	\$ 182,917
2025	46,000	116,250	162,250
2026	46,000	—	46,000
2027	46,000	—	46,000
2028	46,000	—	46,000
Total	\$ 230,000	\$ 253,167	\$ 483,167

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses

such contingent liabilities, and such assessment inherently involves an exercise of judgment. A liability is only recorded if management determines that it is both probable and reasonably estimable.

COVID-19

Based on the current outbreak of SARS-CoV-2, the pathogen responsible for COVID-19, which has already had an impact on financial markets, there could be additional repercussions to the Company's operating business, including but not limited to, the sourcing of materials for product candidates, manufacture of supplies for preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for trials due to such things as quarantines, conduct of patient monitoring and clinical trial data retrieval at investigational study sites.

COVID-19 affected the Company's operations but did not have a material impact on the Company's business, operating results, financial condition or cash flows as of and for the year ended December 31, 2023.

The future impact of the outbreak is highly uncertain and cannot be predicted, and the Company cannot provide any assurance that the outbreak will not have a material adverse impact on the Company's operations or future results or filings with regulatory health authorities. The extent of the impact to the Company, if any, will depend on future developments, including actions taken to contain the coronavirus.

Note 11. Operating Segments

The Company maintains two active operating segments: Specialized BioTherapeutics and Public Health Solutions. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

	For the Years Ended December 31,	
	2023	2022
Revenues		
Specialized BioTherapeutics	\$ 395,124	\$ 31,929
Public Health Solutions	444,235	916,982
Total	<u>\$ 839,359</u>	<u>\$ 948,911</u>
Income (loss) from Operations		
Specialized BioTherapeutics	\$ (2,812,303)	\$ (7,614,988)
Public Health Solutions	(36,531)	26,612
Corporate	(4,849,106)	(6,650,528)
Total	<u>\$ (7,697,940)</u>	<u>\$ (14,238,904)</u>
Amortization and Depreciation Expense		
Specialized BioTherapeutics	\$ 3,932	\$ 10,087
Public Health Solutions	655	1,681
Corporate	1,967	12,794
Total	<u>\$ 6,554</u>	<u>\$ 24,562</u>
Other (Expense) Income, Net		
Specialized BioTherapeutics	\$ 25,267	\$ 102,320
Corporate	(235,860)	(816,690)
Total	<u>\$ (210,593)</u>	<u>\$ (714,370)</u>
Share-Based Compensation		
Specialized BioTherapeutics	\$ 145,683	\$ 138,075
Public Health Solutions	4,782	4,804
Corporate	219,717	190,510
Total	<u>\$ 370,182</u>	<u>\$ 333,389</u>

	As of December 31,	
	2023	2022
Identifiable Assets		
Specialized BioTherapeutics	\$ 272,099	\$ 103,742
Public Health Solutions	3,976	121,290
Corporate	9,521,251	14,054,685
Total	<u>\$ 9,797,326</u>	<u>\$ 14,279,717</u>

Note 12. Subsequent Event

Convertible Debt Financing Agreement

On April 19, 2023, the Company entered into an amendment to the convertible debt financing agreement with Pontifax (See Note 5). The amendment reduced the conversion price with respect to the remaining principal amount outstanding under the agreement. The conversion price was amended to be (i) 90% of the closing price of our common stock on the day before the delivery of the conversion notice with respect to the first 36,790 shares of our common stock issuable upon conversion and (ii) \$27.20 with respect to all shares of our common stock issuable upon conversion in excess of the first 36,790 shares so issued.

Conversion of Promissory Notes

On January 3, 2024, the Company issued an aggregate of 9,139 shares of common stock to two lenders upon conversion of approximately \$100,000 of principal under promissory notes at a conversion price of \$10.88 per share.

Remaining Convertible Debt

As of March 8, 2024, \$2,900,585 of principal and \$45,840 of accrued interest remain outstanding under the agreement. The conversion price for the remaining principal amount as of March 8, 2024 is (i) 90% of the closing price of our common stock on the day before the delivery of the conversion notice with respect to the first 27,651 shares of common stock issuable upon conversion and (ii) \$27.40 with respect to all shares issuable upon conversion in excess of the first 27,651 shares so issued.

Note 13. Reverse Stock Split

On June 5, 2024, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-sixteen, whereby every sixteen shares of the Company's issued and outstanding common stock was automatically combined into one issued and outstanding share of common stock without any change in the par value per share. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. The Company's common stock began trading on The NASDAQ Capital Market on a reverse split basis at the market opening on June 6, 2024. All share and per share data have been restated to reflect this reverse stock split.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Soligenix, Inc.
Princeton, New Jersey

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Soligenix, Inc. (the "Company") as of December 31, 2023, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows the year ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

The financial statements of the Company as of and for the year ended December 31, 2022, before the retrospective adjustments described in Note 13, were audited by other auditors whose report, dated March 31, 2023, expressed an unqualified opinion on those statements. We also audited the adjustments described in Note 13 that were applied to retroactively reflect the one-for-sixteen reverse stock split in the 2022 financial statements. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2022 financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2022 financial statements taken as a whole.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 1. The 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 these financial statements based on our audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides 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 were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Critical Audit Matter Description

As disclosed in Note 5 to the financial statements, on April 19, 2023, the Company amended the convertible debt financing agreement dated December 15, 2020 with Pontifax. The Company has elected the fair value option and has accounted for the Pontifax note at fair value.

There is no current observable market for the Pontifax note and, as such, the Company determined the fair value using the Monte Carlo pricing model. As a result, a high degree of auditor judgment and effort was required in performing audit procedures to evaluate the valuation technique and the significant unobservable inputs.

How the Critical Audit Matter was Addressed in the Audit

Our principal audit procedures performed to address this critical audit matter included the following:

- We obtained an understanding and evaluated the Company's election of accounting policy related to the Pontifax note.
- We obtained an understanding and evaluated the Company's process and methodology used in the valuation of the Pontifax note.
- We reviewed the fair value model used, significant assumptions, and underlying data used in the model and evaluated whether the estimates and assumptions were consistent with audit evidence obtained.
- We evaluated the disclosures surrounding the fair value election with respect to the Pontifax note and ensured that these were disclosed in accordance with the relevant accounting guidance.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2023.

Tampa, Florida

March 15, 2024, except for Note 13, and its related effects to the financial statements, which is as of July 24, 2024.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Soligenix, Inc.

Opinion on the Financial Statements

We have audited, before the effects of the adjustments to retrospectively apply the reverse stock split described in Note 13, the accompanying consolidated balance sheet of Soligenix, Inc and Subsidiaries (the "Company") as of December 31, 2022, and the related consolidated statements of operations, comprehensive loss, changes in mezzanine equity and shareholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the 2022 financial statements, before the effects of the adjustments to retrospectively apply the reverse stock split described in Note 13, present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review or apply any procedures to the adjustments to retrospectively apply the reverse stock split described in Note 13 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by other auditors. (The 2022 financial statements before the effects of the reverse stock split discussed in Note 13 are not presented herein).

Going Concern

The accompanying 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 suffered recurring losses from operations and expects to incur losses for the foreseeable future, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The 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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor from 2010 to 2022.

EISNERAMPER LLP
New York, New York
March 31, 2023



**Up to 1,054,688 Shares of Common Stock
Issuable Upon the Exercise of Previously Issued Common Warrants**

Preliminary Prospectus

July 24, 2024

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses of the Registrant in connection with the offering described in the registration statement. All of the amounts shown are estimated except for the Securities and Exchange Commission (the "SEC") registration fee.

SEC registration fee	\$ 949.60
Legal fees and expenses	\$ 80,000.00
Accounting fees and expenses	\$ 10,000.00
Miscellaneous	\$ 2,000.00
TOTAL	\$ 92,949.60

Item 14. Indemnification of Directors and Officers.

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law grants the Company the power to limit the personal liability of its directors to the Company or its stockholders for monetary damages for breach of a fiduciary duty. Article X of the Company's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Company as follows:

"A Director of the Corporation shall have no personal liability to the corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a

Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Company's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

The Company has a directors' and officers' liability insurance policy.

The above discussion is qualified in its entirety by reference to the Company's Certificate of Incorporation and Bylaws.

Item 15. Recent Sales of Unregistered Securities.

The following is a summary of transactions during the preceding three years involving sales of our securities that were not registered under the Securities Act.

The Company issued (1) a vendor 337 shares of fully vested Common Stock with a fair value of \$148.80 per share on February 7, 2022; (2) a vendor 401 shares of fully vested Common Stock with a fair value of \$124.80 per share on May 6, 2022; (3) a vendor 229 shares of fully vested Common Stock with a fair value of \$218.40 per share on August 5, 2022; (4) a vendor 105 shares of fully vested Common Stock with a fair value of \$115.20 per share on October 4, 2022; (5) a vendor 321 shares of fully vested Common Stock with a fair value of \$156.00 per share on November 7, 2022; (6) a total of 9,139 shares of Common Stock to two lenders upon conversion of approximately \$100,000 of principal under promissory notes at a conversion price of \$10.88 on January 3, 2024; (7) a total of 27,651 shares of Common Stock to two lenders upon conversion of approximately \$154,840 of principal under promissory notes at a conversion price of \$5.60 on April 15, 2024 and (8) warrants to purchase up to 1,054,688 shares of Common Stock to certain investors on July 10, 2024 in exchange for the investors agreeing to exercise for cash existing warrants to purchase 703,125 shares of Common Stock at an exercise price of \$6.00 per share (which includes the \$0.125 charge for the July 2024 Warrants in compliance with the Nasdaq rules).

The issuance of common stock as described above was exempt under Section 4(a)(2) of the Securities Act of 1933, as amended. The recipients are knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about us or had adequate access to information about us. The vendors represented to the Company that the vendors are not "consultants" for purposes of Nasdaq Listing Rule 5635(c).

Item 16. Exhibits and Financial Statement Schedules.

(a) **Exhibits:**

Exhibit No.	Description
2.1	<u>Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).</u>
3.1	<u>Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2012).</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).</u>
3.3	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2016).</u>
3.4	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on October 7, 2016).</u>
3.5	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 14, 2017).</u>
3.6	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our current report on Form 8-K filed on September 28, 2018).</u>
3.7	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of amendment number 1 to current report on Form 8-K filed on December 3, 2020).</u>
3.8	<u>Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020).</u>
3.9	<u>Certificate of Designation of the Series D Preferred Stock of the Company dated December 27, 2022 (incorporated by reference to Exhibit 3.1 to our registration statement on Form 8-A filed on December 27, 2022).</u>
3.10	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of Soligenix, Inc. (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on February 9, 2023).</u>
3.11	<u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of Soligenix, Inc. (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on May 31, 2024).</u>
4.1	<u>Registration Rights Agreement, dated December 15, 2020 by and among Soligenix, Inc. and the other parties named therein (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on December 16, 2020).</u>
4.2	<u>Form of Common Warrant issued in the Company's April 2024 Public Offering (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on April 22, 2024).</u>
4.3	<u>Form of Pre-Funded Warrant issued in the Company's April 2024 Public Offering (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on April 22, 2024).</u>
4.4	<u>Form of Warrant to Purchase Shares of Common Stock issued to certain investors in July 2024 (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on July 9, 2024).</u>
5.1	Opinion of Duane Morris LLP. *

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- 10.1 [License Agreement between the Company and the University of Texas Southwestern Medical Center \(incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB filed March 30, 2004, as amended, for the fiscal year ended December 31, 2004\).](#)
- 10.2 [2005 Equity Incentive Plan, as amended on September 25, 2013 \(incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 30, 2013\).](#) **
- 10.3 [Form S-8 Registration of Stock Options Plan dated December 30, 2005 \(incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005\).](#) **
- 10.4 [Form S-8 Registration of Stock Options Plan dated June 20, 2014 \(incorporated by reference to our registration statement on Form S-8 filed on June 20, 2014\).](#) **
- 10.5 [Form S-8 Registration of Stock Options Plan dated December 11, 2015 \(incorporated by reference to our registration statement on Form S-8 filed on December 14, 2015\).](#) **
- 10.6 [Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company \(incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008\).](#) **
- 10.7 [Exclusive License Agreement dated November 24, 1998, between Enteron Pharmaceuticals, Inc. and George B. McDonald, MD and amendments \(incorporated by reference to Exhibit 10.42 included in our Registration Statement on Form S-1 \(File No. 333-157322\) filed on February 13, 2009\).](#)
- 10.8 [First Amendment to Employment Agreement dated as of July 12, 2011, between the Company and Christopher J. Schaber, PhD \(incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 14, 2011\).](#) **
- 10.9 [Amendment to the Exclusive License Agreement dated as of July 26, 2011, between George McDonald, MD and the Company \(incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 28, 2011\).](#)
- 10.10 [Amendment No. 2 to the Collaboration and Supply Agreement between the Company, Enteron and Sigma-Tau dated as of December 20, 2012 \(incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on December 27, 2012\).](#) †
- 10.11 [Amendment to Exclusive License Agreement dated as of December 20, 2012 between Enteron and McDonald \(incorporated by reference to Exhibit 10.4 of our current report on Form 8-K filed on December 27, 2012\).](#)
- 10.12 [Amendment to Consulting Agreement dated as of December 20, 2012 between Enteron and McDonald \(incorporated by reference to Exhibit 10.5 of our current report on Form 8-K filed on December 27, 2012\).](#)
- 10.13 [Contract HHSO100201300023C dated September 18, 2013 between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority \(incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 24, 2013\).](#) †
- 10.14 [Contract HHSN272201300030C dated September 24, 2013 by and between the Company and the National Institutes of Health \(incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 30, 2013\).](#) †
- 10.15 [Employment Agreement dated as of January 6, 2014 between the Company and Richard Straube, M.D. \(incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on January 8, 2014\).](#) **

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10.16	<u>Asset Purchase Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 5, 2014). †</u>
10.17	<u>Registration Rights Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on September 5, 2014).</u>
10.18	<u>Contract HHSN272201400039C dated September 17, 2014 by and between the Company and the National Institutes of Health (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 23, 2014). †</u>
10.19	<u>Lease Agreement dated November 21, 2014, between the Company and CPP II, LLC (incorporated by reference to Exhibit 10.42 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014).</u>
10.20	<u>At Market Issuance Sales Agreement dated August 11, 2017 between Soligenix, Inc. and FBR Capital Markets & Co. (incorporated by reference to Exhibit 1.1 included in our Quarter Report on Form 10-Q for the fiscal quarter ended June 30, 2017).</u>
10.21	<u>Form of Registration Rights Agreement dated October 31, 2017 (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on October 31, 2017).</u>
10.22	<u>First Amendment to Employment Agreement dated as of April 1, 2019 between the Company and Richard Straube, M.D. (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018).**</u>
10.23	<u>Soligenix, Inc. 2015 Equity Incentive Plan, as amended on June 18, 2017, September 27, 2018, September 6, 2019 and September 22, 2022. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 23, 2022).</u>
10.24	<u>Employment Agreement dated as of September 6, 2019 between the Company and Jonathan L. Guarino (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on September 11, 2019).</u> **
10.25	<u>Second Amendment to Employment Agreement dated as of January 2, 2020, between Soligenix, Inc. and Christopher J. Schaber, PhD (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 3, 2020). **</u>
10.26	<u>Amendment No. 1 to At Market Issuance Sales Agreement dated August 28, 2020 between Soligenix, Inc. and B. Riley FBR, Inc. (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on August 28, 2020).</u>
10.27	<u>Third Extension and Amendment to Lease dated July 7, 2020 between CPP II LLC and Soligenix, Inc. (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020).</u>
10.28	<u>Loan and Security Agreement, dated December 15, 2020. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 16, 2020).</u>
10.29	<u>Third Amendment to Employment Agreement dated as of December 10, 2020, between Soligenix, Inc. and Christopher J. Schaber, PhD. (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on December 16, 2020). **</u>
10.30	<u>Form S-8 registration statement relating to Soligenix, Inc. 2015 Equity Incentive Plan (incorporated by reference to our registration statement on Form S-8 filed on October 28, 2022). **</u>

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10.31	First Amendment to Loan and Security Agreement, dated April 19, 2023 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on April 19, 2023).
10.32	Form of Securities Purchase Agreement executed in connection with the Company's April 2024 Public Offering (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on April 22, 2024).
10.33	Form of Warrant Inducement Agreement, by and between the Company and each Holder (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on July 9, 2024).
21.1	Subsidiaries of the Company. *
23.1	Consent of Cherry Bekaert LLP. *
23.2	Consent of EisnerAmper LLP. *
23.3	Consent of Duane Morris LLP (included in Exhibit 5.1). *
24.1	Power of Attorney (included on signature page). *
107	Filing Fee Table. *
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

- (b) **Consolidated Financial Statement Schedules:** All schedules are omitted because the required information is inapplicable or the information is presented in the consolidated financial statements and the related notes.

Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed

that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this Registration Statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referenced in Item 14 of this Registration Statement, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(i) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Princeton, State of New Jersey, on the 24th day of July, 2024.

SOLIGENIX, INC.

By: /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
Chief Executive Officer and President

KNOW ALL BY THESE PRESENTS, each person whose signature appears below appoints Christopher J. Schaber and Jonathan Guarino, and each of them, any of whom may act without the joinder of the other, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him or her and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or would do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed below by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
By: <u>/s/ Christopher J. Schaber</u> Christopher J. Schaber, PhD	Chairman, President and Chief Executive Officer (Principal Executive Officer)	July 24, 2024
By: <u>/s/ Gregg A. Lapointe</u> Gregg A. Lapointe, CPA	Director	July 24, 2024
By: <u>/s/ Diane L. Parks</u> Diane L. Parks, MBA	Director	July 24, 2024
By: <u>/s/ Robert J. Rubin</u> Robert J. Rubin, MD	Director	July 24, 2024
By: <u>/s/ Jerome B. Zeldis</u> Jerome B. Zeldis, MD, PhD	Director	July 24, 2024
By: <u>/s/ Jonathan Guarino</u> Jonathan Guarino, CPA	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	July 24, 2024

Duane Morris LLP
Boca Center Tower II
5100 Town Center Circle, Suite 400
Boca Raton, FL 33486-1008

July 24, 2024

Soligenix, Inc.
29 Emmons Drive, Suite B-10
Princeton, New Jersey 08540

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Soligenix, Inc., a Delaware corporation (the "Company"), in connection with the preparation and filing with the U.S. Securities and Exchange Commission (the "Commission"), pursuant to the Securities Act of 1933, as amended (the "Securities Act"), of the Registration Statement on Form S-1 of the Company (the "Registration Statement"), relating to the resale of up to 1,054,688 shares (collectively, the "Resale Shares") of common stock, par value \$0.001 per share ("Common Stock"), consisting of shares of Common Stock issuable upon the exercise of outstanding warrants to purchase Common Stock (collectively, the "Warrants"), that were issued to certain holders pursuant to that certain Warrant Inducement Agreement dated as of July 9, 2024 (the "Warrant Inducement Agreement"), among the Company and the holders party thereto (the "Holders").

This opinion letter is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related prospectus (the "Prospectus"), other than as expressly stated herein with respect to the issuance of the Resale Shares.

In connection with the opinion expressed herein, we have examined such documents, records and matters of law as we have deemed relevant or necessary for purposes of rendering such opinion, including, without limitation:

- (a) the Registration Statement, in the form to be filed with the Commission, the exhibits filed or to be filed in connection therewith, and the form of Prospectus contained therein;
- (b) the Company's Certificate of Incorporation, as amended;
- (c) the Company's Bylaws, as amended;
- (d) a certificate, dated as of July 19, 2024, from the Secretary of State of the State of Delaware certifying as to the existence and good standing of the Company under the laws of the State of Delaware (the "Good Standing Certificate");
- (e) the resolutions adopted by the Board of Directors of the Company relating to, among other things, the approval of the Warrant Inducement Agreement and the Warrants, and the registration, sale and issuance of the Resale Shares;
- (f) the Warrants; and
- (g) such other documents as we have deemed necessary or appropriate to enable us to render the opinion expressed below.

In such examination and in rendering the opinion expressed below, we have assumed, without independent investigation or verification: (i) the genuineness of all signatures on all agreements, instruments, corporate records, certificates and other documents submitted to us; (ii) the authenticity and completeness of all agreements, instruments, corporate records, certificates and other documents submitted to us as originals; (iii) that all agreements, instruments, corporate records, certificates and other documents submitted to us as certified, electronic, facsimile, conformed, photostatic or other copies conform to the originals thereof, and that such originals are authentic and complete; (iv) the legal competency, capacity and authority of all persons executing all agreements, instruments, corporate records, certificates and other documents submitted to us; (v) the due authorization, execution and delivery of all agreements, instruments, corporate records, certificates and other documents by all parties thereto (other than the Company); (vi) that no documents submitted to us have been amended or terminated orally or in writing, except as has been disclosed to us in writing; (vii) that the statements contained in the certificates and comparable documents of public officials, officers and representatives of the Company and other persons on which we have relied for the purposes of this opinion letter are true and correct on and as of the date hereof; (viii) that there has not been and there will not be any change in the good standing status of the Company from that reported in the Good Standing

Certificate; (ix) that each of the officers and directors of the Company has properly exercised his or her fiduciary duties; (x) that the Resale Shares will not be issued or transferred in violation of any restriction contained in the Certificate of Incorporation and that upon issuance of any of the Resale Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under the Certificate of Incorporation and by the Company's Board of Directors (or an authorized committee thereof) in connection with the Warrant Inducement Agreement and the Warrants, (xi) the resolutions authorizing the Company to issue and deliver the Resale Shares pursuant to the Warrants by the Company's Board of Directors (or an authorized committee thereof) will be in full force and effect at all times at which such Resale Shares are issued and delivered by the Company, and the Company will take no action inconsistent with such resolutions; (xii) that at or prior to the time of the issuance and delivery of the Resale Shares, the Registration Statement will have been declared effective under the Securities Act and such effectiveness shall not have been terminated or rescinded; (xiii) that the exercise price of the Warrants will not be adjusted to an amount below the par value of the Common Stock; (xiv) that the Warrant Inducement Agreement executed by the Holders is in substantially the form previously provided to us to review and (xv) the Company will comply with all applicable requirements regarding uncertificated shares provided in the General Corporation Law of the State of Delaware (the "DGCL"). We have also assumed that the Resale Shares will be issued and sold as described in the Registration Statement and in accordance with the terms of the Warrant Inducement Agreement and the Warrants. With respect to the Warrants and the Resale Shares, we express no opinion to the extent that, notwithstanding the Company's current reservation of shares of Common Stock, future issuances of securities of the Company, including the Resale Shares and/or antidilution adjustments to outstanding securities of the Company, including the Warrants, may cause the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized but unissued.

Based on the foregoing, and subject to the further assumptions, qualifications and limitations set forth herein, we are of the opinion that the Resale Shares, when issued upon exercise of the Warrants pursuant to the terms of the Warrants against payment of the exercise price therefor as provided in the Warrants, will be validly issued, fully paid and non-assessable.

The opinion expressed herein is limited to the DGCL, as in effect on the date hereof, and we express no opinion as to the effect of the laws of any other jurisdiction on the opinion expressed herein.

This opinion letter is given as of the date hereof, and we express no opinion as to the effect of subsequent events or changes in law occurring or becoming effective after the date hereof. We assume no obligation to update this opinion letter or otherwise advise you with respect to any facts or circumstances or changes in law that may hereafter occur or come to our attention.

Our opinions expressed herein are limited to the matters expressly stated herein, and no opinion is implied or may be inferred beyond the matters expressly stated.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement, and to the reference to the firm under the caption "Legal Matters" in the prospectus constituting a part of such Registration Statement. In rendering this opinion letter and giving this consent, we do not hereby admit that we are included in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Duane Morris LLP

DUANE MORRIS LLP

SUBSIDIARIES OF SOLIGENIX, INC.

The following represents a list of Soligenix, Inc.'s subsidiaries:

Name	Ownership		State of Incorporation
Enteron Pharmaceuticals, Inc.	100.00	%	Delaware
Orasomal Technologies Inc.	75.30	%	Delaware
Soligenix BioPharma Canada Incorporated	100.00	%	Canada
Soligenix UK Limited	100.00	%	United Kingdom
Soligenix NE B.V.	100.00	%	Netherlands
Soligenix Biopharma HI, Inc.	100.00	%	Hawaii

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement of Soligenix, Inc. on Form S-1 to be filed on or about July 24, 2024 of our report dated March 15, 2024, except for Note 13, and its related effects to the financial statements, which is as of July 24, 2024, with respect to our audit of the financial statements as of December 31, 2023 and for the year then ended and the adjustments described in Note 13 that were applied to retroactively reflect the one-for-sixteen reverse stock split in the 2022 financial statements. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to the reference to our firm under the caption "Experts" in this Registration Statement.

/s/ Cherry Bekaert LLP

Tampa, Florida
July 24, 2024

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement of Soligenix, Inc. on Form S-1 to be filed on or about July 24, 2024 of our report dated March 31, 2023, on our audit of the financial statements as of December 31, 2022 and for the year then ended, before the effects of the adjustments to retrospectively apply the reverse stock split as described in Note 13 to the financial statements for the year ended December 31, 2022, which report appears in this Registration Statement. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to the reference to our firm under the caption "Experts" in this Registration Statement.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
July 24, 2024

Calculation of Filing Fee Table

FORM S-1
(Form Type)

Soligenix, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rate	Amount Registered	Maximum Aggregate Offering Price (1)	Fee Rate	Amount of Registration Fee
Fees to be Paid	Equity	Common Stock issuable upon exercise of Common Warrants	457(c)	1,054,688	\$ 6,433,597	0.0001476	\$ 949.60
		Total Offering Amount:			\$ 6,433,597		\$ 949.60
		Total Fees Previously Paid:					-
		Total Fee Offsets:					-
		Net Fee Due:					\$ 949.60

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the high and low sales price of our common stock of \$6.10 as reported on the Nasdaq Capital Market on July 19, 2024.