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

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2024

or

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

For the transition period from _____ to _____

Commission File No. 001-14778

SOLIGENIX, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

29 EMMONS DRIVE, SUITE B-10 PRINCETON, NJ	**08540**
(Address of principal executive offices)	(Zip Code)

(609) 538-8200

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.001 per share	**SNGX**	**The Nasdaq Capital Market**

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

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

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

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

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

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

As of May 3, 2024, 15,799,837 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2024	December 31, 2023
Assets	**(unaudited)**	
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	**$ 8,058,385**	$ 9,797,326
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	**7,290,013**	7,274,904
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, $.001 par value; 75,000,000 shares authorized; 10,524,437 and 10,378,238 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	**10,524**	10,378
Additional paid-in capital	**228,353,208**	228,193,977
Accumulated other comprehensive income	**24,143**	22,243
Accumulated deficit	**(227,619,503)**	(225,704,176)
Total shareholders' equity	**768,372**	2,522,422
Total liabilities and shareholders' equity	**$ 8,058,385**	$ 9,797,326

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	**$ (0.18)**	$ (0.36)
Basic and diluted weighted average common shares outstanding	**10,521,233**	2,914,929

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	**$ (1,913,427)**	$ (1,058,262)

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	Accumulated Other Comprehensive	Accumulated	
	Shares	Par Value	Shares	Par Value	Capital	Income (Loss)	Deficit	Total
Balance, December 31, 2023	**—**	**$ —**	**10,378,238**	**$ 10,378**	**$228,193,977**	**$ 22,243**	**$(225,704,176)**	**$ 2,522,422**
Issuance of common stock associated with conversion of debt			146,199	146	99,270	—	—	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	**—**	**$ —**	**10,524,437**	**$ 10,524**	**$228,353,208**	**$ 24,143**	**$(227,619,503)**	**$ 768,372**

	Mezzanine Equity-Series D Preferred Stock		Common Stock		Additional Paid–In	Accumulated Other Comprehensive	Accumulated	
	Shares	Par Value	Shares	Par Value	Capital	Income (Loss)	Deficit	Total
Balance, December 31, 2022	**—**	**$ 43**	**2,908,578**	**$ 2,909**	**$217,064,964**	**$ 24,747**	**$(219,563,446)**	**$(2,470,826)**
Sale of common stock pursuant to B. Riley At Market Issuance Sales Agreement			21,195	21	70,709	—	—	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	**—**	**$ —**	**2,929,773**	**$ 2,930**	**$217,206,966**	**$ 12,594**	**$(220,609,555)**	**$(3,387,065)**

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 3,275,000 shares of its common stock, pre-funded warrants to purchase 8,600,000 shares of its common stock and common warrants to purchase up to 11,875,000 shares of its common stock at a combined public offering price of $0.40.

The pre-funded warrants have an exercise price of $0.001. The common warrants have an exercise price of $0.40 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 ($4.3 net) 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. 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	**6,538,073**	—
Stock options	**906,226**	192,273
Convertible debt	**2,008,100**	146,342
Total	**9,452,399**	338,615

The weighted average exercise prices of the Company's warrants and stock options outstanding at March 31, 2024 were $1.50 and $5.52 per share, respectively. The weighted average exercise prices of the Company's stock options outstanding at March 31, 2023 was $27.56 per share. The weighted average conversion price of the Company's convertible debt at March 31, 2024 and 2023 was $1.44 and $61.50 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 588,599 shares of the Company's common stock issuable upon conversion and to (ii) $1.70 with respect to all shares of the Company's common stock issuable upon conversion in excess of the first 588,599 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. 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 146,199 shares of fully vested common stock pursuant to conversion of a portion of the convertible debt principal balance at a conversion price of $0.68 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 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 GAAP. In March 2020, the Company issued 130,413 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 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	$ 230,000	$ 219,067	$ 449,067

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	**$ 117,029**	$ 257,178
Income (loss) from Operations		
Specialized BioTherapeutics	**$ (860,604)**	$ (910,377)
Public Health Solutions	**(45,997)**	427
Corporate	**(1,210,490)**	(1,240,739)
Total	**$ (2,117,091)**	$ (2,150,689)
Amortization and Depreciation Expense		
Specialized BioTherapeutics	**$ 953**	$ 1,071
Public Health Solutions	**159**	178
Corporate	**476**	536
Total	**$ 1,588**	$ 1,785
Other (Expense) Income, Net		
Specialized BioTherapeutics	**$ 7,540**	$ 6,082
Corporate	**194,224**	(62,699)
Total	**$ 201,764**	$ (56,617)
Share-Based Compensation		
Specialized BioTherapeutics	**$ 20,672**	$ 27,427
Public Health Solutions	**588**	994
Corporate	**38,701**	45,213
Total	**$ 59,961**	$ 73,634

	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	**$ 8,058,385**	$ 9,797,326

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 442,400 shares of the Company's common stock at $0.35 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) 3,275,000 shares of the Company's common stock, (ii) pre-funded warrants to purchase 8,600,000 shares of the Company's common stock and (iii) common warrants to purchase 11,875,000 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 $0.40. Each unit comprised of pre-funded warrants and common warrants was sold at a per unit price of $0.399, which represents the same per unit price less the $ 0.001 per share exercise price of the pre-funded warrants. The common warrants are exercisable at a price of $0.40 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 ($4.3 net) million before deducting commissions and other estimated offering expenses payable by the Company.

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited condensed consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes, Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2023. We provide addresses to internet sites solely for the information to investors. We do not intend any addresses to be active links or to otherwise incorporate the contents of any website into this report.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are not guarantees of future performance and are subject to significant risks, uncertainties, assumptions and other factors, which are difficult to predict and may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this report may be identified by words such as "believes," "anticipates," "expects," "intends," "may," "would," "will" and other similar expressions. However, these words are not the exclusive means of identifying these statements. Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets related to our business and are forward-looking statements.

Actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors which may affect these actual outcomes and results include, without limitation:

- *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; and*

- *other factors, including those "Risk Factors" set forth under Part II, Item 1A. "Risk Factors" in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2023.*

Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-Q with the United States ("U.S.") Securities and Exchange Commission (the "SEC") or for any other reason. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Note Regarding Reverse Nasdaq Capital Market Listing Requirements

On June 23, 2023, we received a letter from the staff (the "Staff") of the Listing Qualifications Department of the Nasdaq Stock Market indicating that, based upon the closing bid price of our common stock for the 30 consecutive business day period between May 9, 2023 through June 22, 2023, we 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 we 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). We were unable to regain compliance prior to the expiration of the 180-day period.

On December 21, 2023, we received another written notice (the "Notice") from the Staff stating that we had not complied with the minimum bid price requirement and were not eligible for a second 180-day period because we did not comply with the $5,000,000 minimum stockholders' equity initial listing requirement for Nasdaq. As a result, the Notice indicated that our common stock would be suspended from trading on Nasdaq unless we requested a hearing before the Nasdaq Hearings Panel by December 28, 2023. On March 26, 2024, we had an oral hearing with a Nasdaq Hearings Panel to appeal the Staff's 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.

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

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, our 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.

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.

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

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
		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 ≥ 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/cm^2 twice weekly. This will be increased upwards by 2 J/cm^2 until: 1) the patient experiences a Grade 1 erythema, 2) the patient reaches the maximum dose of 30 J/cm^2, 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 a prestigious academic institution that 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.

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, melioidosis), 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:
    - before the infectious organism and/or its antibiotic susceptibility is known; or
    - in at-risk populations prior to infection.
- An ability to be used as an additive, complementary treatment with antibiotics, thereby:
    - enhancing efficacy of sub-optimal antibiotic regimens (e.g., partially antibiotic-resistant infections);
    - enhancing clearance of infection, thereby minimizing the generation of antibiotic resistance (e.g., in treating melioidosis); and
    - 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.

Intellectual Property

In addition to orphan drug exclusivity, we maintain patent and other intellectual property protection in the U.S. and other countries with respect to our technology and product candidates. We seek to protect our proprietary position in reliance upon trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. ("GAAP"). 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 appearing at the beginning of this Quarterly Report on Form 10-Q, 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 GAAP 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.

Material 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, 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.

Financial Condition

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), 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 3,275,000 shares of our common stock, pre-funded warrants to purchase 8,600,000 shares of our common stock and common warrants to purchase up to 11,875,000 shares of our common stock at a combined public offering price of $0.40. The pre-funded warrants have an exercise price of $0.001. The common warrants have an exercise price of $0.40 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 ($4.3 net) million before deducting commissions and other estimated offering expenses. We plan to use the proceeds for further support of our programs, as well as for working capital. See Note 8; 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.

Nasdaq Capital Market Listing Requirements

On June 23, 2023, we 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 our common stock for the 30 consecutive business day period between May 9, 2023 through June 22, 2023, we 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 we 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). We were unable to regain compliance prior to the expiration of the 180-day period.

On December 21, 2023, we received another written notice (the "Notice") from the Staff stating that we had not complied with the minimum bid price requirement and was not eligible for a second 180-day period because we did not comply with the $5,000,000 minimum stockholders' equity initial listing requirement for Nasdaq. As a result, the Notice indicated that our common stock would be suspended from trading on Nasdaq unless we requested a hearing before the Nasdaq Hearings Panel by December 28, 2023. On March 26, 2024, we 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, our common stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the compliance period.

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

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 588,599 shares of our common stock issuable upon conversion and to (ii) $1.70 with respect to all shares of our common stock issuable upon conversion in excess of the first 588,599 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.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities, in addition to the foreign exchange rate fluctuations related to our foreign currency transactions. We do not have any derivative financial instruments. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) are (1) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2024, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) using the criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission (“COSO”) in Internal Control – Integrated Framework (2013 Framework). Our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded, based upon the evaluation described above, that as of March 31, 2024, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting identified in connection with the evaluation of such internal controls that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II - OTHER INFORMATION.

ITEM 1 – 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.

ITEM 1A – RISK FACTORS

Our business faces significant risks. These risks include those disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023. If any of the events or circumstances described in the referenced risks actually occur, our business, financial condition or results of operations could be materially adversely affected and such events or circumstances could cause our actual results to differ materially from the results contemplated by the "forward-looking" statements contained in this report. These risks should be read in conjunction with the other information set forth in this Quarterly Report as well as in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in our periodic reports on Form 10-Q and Form 8-K. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements, except as required by law.

Shareholders may suffer substantial dilution related to issued pre-funded warrants, common stock warrants, options and convertible notes.

As of May 3, 2024, we had a number of agreements or obligations that may result in dilution to investors. These include:

- pre-funded warrants to purchase a total of 7,042,000 shares of our common stock at a current weighted average exercise price of $0.001 per share;
- common stock warrants to purchase a total of 18,413,073 shares of our common stock at a current weighted average exercise price of $0.79;
- options to purchase approximately 906,226 shares of our common stock at a current weighted average exercise price of $5.52; and
- convertible promissory notes issued to Pontifax Medison Finance, of which there was $2,745,745 of principal and $21,529 of accrued interest outstanding, which notes are convertible at $1.70 per share; and
- 5,096,447 shares of common stock available for future issuance under our 2015 Equity Incentive Plan.

We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants under our incentive compensation plan. To the extent that pre-funded warrants, common stock 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 pre-funded warrants, common stock 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.

ITEM 5 – OTHER INFORMATION

During the quarter ended March 31, 2024, no directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6 – EXHIBITS

EXHIBIT NO.	DESCRIPTION
31.1	Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Schema
101.CAL	Inline XBRL Taxonomy Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Definition Linkbase
101.LAB	Inline XBRL Taxonomy Label Linkbase
101.PRE	Inline XBRL Taxonomy Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLIGENIX, INC.

May 10, 2024

By /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
President and Chief Executive Officer
(Principal Executive Officer)

May 10, 2024

By /s/ Jonathan Guarino
Jonathan Guarino
Chief Financial Officer, Senior Vice President,
and Corporate Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Christopher J. Schaber, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Soligenix, Inc. for the fiscal quarter ended March 31, 2024;

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

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

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

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

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

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

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

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

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

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

May 10, 2024

/s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Jonathan Guarino, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Soligenix, Inc. for the fiscal quarter ended March 31, 2024;

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

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

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

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

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

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

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

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

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

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

May 10, 2024

/s/ Jonathan Guarino
Jonathan Guarino
Senior Vice President and Chief Financial Officer

EXHIBIT 32.1

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

In connection with this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

May 10, 2024

/s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer

EXHIBIT 32.2

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

In connection with this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

May 10, 2024

/s/ Jonathan Guarino
Jonathan Guarino
Senior Vice President and Chief Financial Officer