SOLIGENIX, INC.

FORM 10-Q
(Quarterly Report)

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Address	29 EMMONS DRIVE SUITE B-10 PRINCETON, NJ, 08540
Telephone	609-538-8200
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Industry	Biotechnology & Medical Research
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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, 2025

or

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

For the transition period from _____ to _____

Commission File 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 2, 2025, 3,264,346 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, 2025	December 31, 2024
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	**$ 7,297,171**	$ 7,819,514
Deferred issuance cost	**43,836**	103,847
Prepaid expenses and other current assets	**299,735**	905,269
Total current assets	**7,640,742**	8,828,630
Security deposit	**22,777**	22,777
Office furniture and equipment, net	**5,505**	6,113
Right-of-use lease assets	**77,096**	108,963
Total assets	**$ 7,746,120**	$ 8,966,483
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	**$ 599,688**	$ 667,896
Accrued expenses	**3,404,332**	2,359,339
Accrued compensation	**50,537**	336,442
Lease liabilities, current	**79,125**	111,862
Convertible debt	**—**	1,372,873
Total liabilities	**4,133,682**	4,848,412
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, 350,000 shares authorized; none issued or outstanding at March 31, 2025 and December 31, 2024, respectively	—	—
Common stock, $.001 par value; 75,000,000 shares authorized; 3,183,992 and 2,514,499 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively[1]	**3,183**	2,514
Additional paid-in capital [1]	**240,770,981**	238,040,520
Accumulated other comprehensive income	**45,789**	45,789
Accumulated deficit	**(237,207,515)**	(233,970,752)
Total shareholders' equity	**3,612,438**	4,118,071
Total liabilities and shareholders' equity	**$ 7,746,120**	$ 8,966,483

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, 2025 and 2024
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenues:		
Grant revenue	**$ —**	$ 117,029
Total revenues	**—**	117,029
Cost of revenues	**—**	(117,029)
Gross profit	**—**	—
Operating expenses:		
Research and development	**2,227,175**	1,095,040
General and administrative	**1,084,828**	1,022,051
Total operating expenses	**3,312,003**	2,117,091
Loss from operations	**(3,312,003)**	(2,117,091)
Other income (expense):		
Foreign currency transaction (loss) gain	**(788)**	1,209
Interest income, net	**76,028**	28,842
Research and development incentives	**—**	6,331
Change in fair value of convertible debt	**—**	165,382
Total other income	**75,240**	201,764
Net loss applicable to common stockholders	**$ (3,236,763)**	$ (1,915,327)
Basic and diluted net loss per share [1]	**$ (1.06)**	$ (2.91)
Basic and diluted weighted average common shares outstanding [1]	**3,049,625**	657,698

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, 2025 and 2024
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Net loss	**$ (3,236,763)**	$ (1,915,327)
Other comprehensive income (loss):		
Foreign currency translation adjustments	**—**	1,900
Comprehensive loss	**$ (3,236,763)**	$ (1,913,427)

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
For the Three Months Ended March 31, 2025 and 2024
(Unaudited)

	Common Stock		Additional Paid–In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balance, December 31, 2024	**2,514,499**	**$ 2,514**	**$ 238,040,520**	**$ 45,789**	**$ (233,970,752)**	**$ 4,118,071**
Issuance of common stock pursuant to At Market Issuance Sales Agreement	657,147	657	2,696,885	—	—	2,697,542
Issuance costs associated with sales of common stock pursuant to At Market Issuance Sales Agreement	—	—	(60,011)	—	—	(60,011)
Issuance of common stock to vendors	12,346	12	29,988			30,000
Share-based compensation expense	—	—	63,599	—	—	63,599
Net loss	—	—	—	—	(3,236,763)	(3,236,763)
Balance, March 31, 2025	**3,183,992**	**$ 3,183**	**$ 240,770,981**	**$ 45,789**	**$ (237,207,515)**	**$ 3,612,438**

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

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, 2025 and 2024
(Unaudited)

	2025	2024
Operating activities:		
Net loss	**$ (3,236,763)**	$ (1,915,327)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	**608**	1,588
Non-cash lease expense	**31,867**	29,265
Share-based compensation	**63,599**	59,961
Issuance of common stock to vendors for services	**30,000**	—
Change in fair value of convertible debt	**—**	(165,382)
Change in operating assets and liabilities:		
Contracts and grants receivable	**—**	54,225
Prepaid expenses and other current assets	**605,534**	414,138
Research and development incentives receivable	**—**	17,379
Operating lease liability	**(32,737)**	(29,359)
Accounts payable and accrued expenses	**976,785**	391,929
Accrued compensation	**(285,905)**	(200,899)
Net cash flows from operating activities	**(1,847,012)**	(1,342,482)
Financing activities:		
Proceeds from issuance of common stock pursuant to At Market Issuance Sales Agreement	**2,697,542**	—
Issuance costs associated with public offerings	**—**	(8,992)
Convertible debt repayments	**(1,372,873)**	—
Net cash flows from financing activities	**1,324,669**	(8,992)
Effect of exchange rate on cash and cash equivalents	**—**	(3,136)
Net decrease in cash and cash equivalents	**(522,343)**	(1,354,610)
Cash and cash equivalents at beginning of year	**7,819,514**	8,446,158
Cash and cash equivalents at end of year	**$ 7,297,171**	$ 7,091,548
Supplemental information:		
Cash paid for state income taxes	**$ 56,169**	$ 17,965
Cash paid for interest	**$ 35,044**	$ 64,047
Cash paid for lease liabilities:		
Operating lease	**$ 34,875**	$ 34,100
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	**$ 60,011**	$ —
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 successful completion of the first Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study and 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 began patient enrollment during December 2024 for the second Phase 3 study, called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2). The Company anticipates top-line results in the second half of 2026. Upon successful completion of the Phase 3 FLASH2 study, regulatory approval will be sought to support potential commercialization worldwide.

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

The Company's Public Health Solutions business segment includes development programs for (i) RiVax®, a ricin toxin vaccine candidate, (ii) SGX943, a therapeutic candidate for antibiotic resistant and emerging infectious disease, and (iii) various vaccine programs, including a program targeting filoviruses (such as Marburg and Ebola) and CiVax™, a 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, 2025 are not necessarily indicative of results that may be expected for the full year.

Liquidity

The Company has evaluated whether conditions and events, considered in the aggregate, raise substantial doubt about its ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued. As of March 31, 2025, the Company had an accumulated deficit of $237,207,515 and working capital of $3,507,060. For the three months ended March 31, 2025, the Company incurred a net loss of $3,236,763 and used $1,847,012 of cash in operating activities. The Company expects to continue generating losses in the foreseeable future, and its liquidity needs will depend largely on budgeted operational expenditures related to the advancement of its product candidates.

Management believes that the Company has sufficient resources to support development activities, business operations, and meet its obligations through the fourth quarter of 2025. However, as of the date of filing this Quarterly Report on Form 10-Q, the Company does not have sufficient cash and cash equivalents to fund operations for at least 12 months following the issuance of these financial statements. These factors raise substantial doubt about the Company's ability to continue as a going concern.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, the Company's plans include securing:

- additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations.

- additional proceeds from government contract and grant programs.

- additional proceeds from the sale of shares of the Company's common stock via the At Market Issuance Sales Agreement ("AGP Sales Agreement") with A.G.P/Alliance Global Partners ("AGP").

While the AGP Sales Agreement is in place, none of the other funding alternatives are currently committed. There is no assurance that the Company will be successful in securing sufficient financing on acceptable terms, if at all. Failure to obtain adequate funding may require the Company to delay, reduce, or eliminate certain business activities and development programs, materially impacting its financial condition and results of operations.

Additionally, macroeconomic and geopolitical uncertainties may further restrict access to capital, exacerbating liquidity challenges. Furthermore, concerns regarding the Company's ability to continue as a going concern could negatively impact relationships with business partners, vendors, and other stakeholders.

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.

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

- The Company has up to approximately $554,000 in active government grant funding still available as of March 31, 2025 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 will continue 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 remains 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 has up to approximately $1.8 million remaining from the AGP Sales Agreement as of May 2, 2025 under the prospectus supplement dated August 16, 2024. From April 1, 2025 through May 2, 2025, the Company sold 80,354 shares of common stock pursuant to the AGP Sales Agreement at a weighted average price of $2.41 per share for total gross proceeds of approximately $194,000.

- 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.

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, continue enrollment and execution of 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.

- Expand 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.

- Expand development of dusquetide under the research name SGX945 into BD by conducting 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.

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 ("CODM"), which is the Company's Chief Executive Officer, 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 did not record any impairment of long-lived assets for the three months ended March 31, 2025 and 2024.

Fair Value of Financial Instruments

Fair Value is defined 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. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on March 31, 2025. 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.

Fair Value valuation techniques include a three level hierarchy 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, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

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.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with applicable accounting guidance. 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). 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, 2025 and 2024.

Foreign Currency Transactions and Translation

The Company's UK Subsidiary's functional currency, the British Pound, is translated into the U.S. Dollar for reporting purposes during consolidation, with related translation adjustments reported as a cumulative translation adjustment, which is a component of accumulated other comprehensive income. The Company recognizes foreign currency related transaction gains or losses as a component of net loss when incurred. Such transaction related foreign currency gains or losses were de minimus for the three months ended March 31, 2025 and 2024, respectively.

Loss Per Share

Basic earnings per share ("EPS") is computed by dividing loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period.

The following table summarizes outstanding instruments which were not included in the computation of diluted EPS as to do so would have been antidilutive:

	As of March 31,	
	2025	**2024**
Common stock purchase warrants	**1,467,581**	408,640
Stock options	**229,919**	56,568
Convertible debt	**—**	335,716
Total	**1,697,500**	800,924

Use of Estimates and Assumptions

The preparation of financial statements 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, 2025	December 31, 2024
Clinical trial expenses	$ 1,388,546	$ 1,135,542
Other	2,015,786	1,223,797
Total	**$ 3,404,332**	$ 2,359,339

Note 4. Debt

In December 2020, the Company entered into a $20 million convertible debt financing agreement with Pontifax (the "Loan Agreement"). Under the terms of the Loan Agreement, 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 on 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.

In April 2023, the Company entered into an amendment to the Loan Agreement (the "2023 Amendment"). The 2023 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 2023 Amendment also provided for interest only through June 30, 2024, reduced quarterly principal repayments to $750,000, and eliminated the minimum cash covenant. Further, the 2023 Amendment reduced the conversion price with respect to the remaining principal amount to (i) 90% of the closing price of the Company's common stock on the day before the delivery of a conversion notice with respect to the first 36,790 shares of the Company's common stock issuable upon conversion and to (ii) $27.20 with respect to all shares of the Company's common stock issuable upon conversion thereafter. The remaining terms of the agreement remained unmodified.

On January 3, 2024, Pontifax delivered a conversion notice to the Company electing to convert a portion of the remaining principal balance into shares of the Company's common stock. Upon conversion, the Company issued 9,139 shares of the Company's common stock at $10.88 per share, reducing the remaining principal balance by $99,416.

On April 15, 2024, Pontifax delivered a conversion notice to the Company electing to convert a portion of the remaining principal balance into shares of the Company's common stock. Upon conversion, the Company issued 27,651 shares of the Company's common stock at $5.60 per share, reducing the remaining principal balance by $154,840.

The 2023 Amendment resulted in the extinguishment of the original convertible debt for accounting purposes. The Company elected to account for the amended convertible debt using the fair value option. As a result, the Company recognized $0 and $165,382 of other income from the change in the fair value of the convertible debt in its accompanying condensed consolidated statements of operations during the three months ended March 31, 2025 and 2024, respectively. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

In October 2024, the Company entered into an amendment (the "2024 Amendment") to the Loan Agreement, as amended. The 2024 Amendment reduced the conversion price with respect to the remaining principal amount outstanding to (i) $3.81 for the first 501,648 shares of the Company's common stock issuable upon conversion and (ii) $4.23 with respect to all shares of the Company's common stock issuable upon conversion thereafter. The remaining terms of the agreement continued in effect with minimal, non-material modifications to those terms.

In February 2025, the Company fully repaid all outstanding obligations and terminated the Loan Agreement. As a result, all related liens and security interests securing the Company's obligations were released. The Company did not incur any prepayment penalties for the early repayment.

Note 5. Shareholders' Equity

Common Stock

Common stock transactions for the three months ended March 31, 2025 are as follows:

- The Company issued a vendor 12,346 shares of common stock with a fair value of $2.43 per share.
- The Company sold 657,147 shares of common stock pursuant to the AGP Sales Agreement at a weighted average price of $4.15 per share.

The issuance of the Company's common stock to the vendor described above was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended. The recipient is knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about the Company or had adequate access to information about the Company. The vendor represented to the Company that the vendor is not a "consultant" for purposes of Nasdaq Listing Rule 5635(c). The issuance of the Company's common stock pursuant to the AGP Sales Agreement described above was registered on a Registration Statement on Form S-3.

AGP At Market Issuance Sales Agreement

In August 2024, the Company entered into the AGP Sales Agreement to sell shares of the Company's common stock from time to time, through an "at-the-market" equity offering program (the "AGP ATM"). In connection with the sale of shares via the AGP ATM, the Company determines, among other things, the number of shares to be issued, the time period during which sales may be requested to be made, limitation on the number of shares that may be sold in any one trading day, and any minimum price below which sales may not be made. Pursuant to the terms, AGP is entitled to compensation for its services in an amount up to 3% of the gross proceeds from the sale of shares under the AGP ATM. The Company has no obligation to sell any shares under the AGP ATM, and may suspend solicitation and offers at any time. The AGP ATM may be terminated by the Company or AGP upon notice, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse change in the Company. The AGP ATM will terminate upon the earliest of (a) December 15, 2026, (b) the sale of all of the shares of common stock subject to the AGP ATM, (c) the termination of the AGP Sales Agreement as permitted therein, or (d) the mutual agreement of the parties.

The AGP Sales Agreement provides for the offer and sale of shares of common stock having an aggregate offering price of up to $5.8 million. As of May 2, 2025, there was approximately $1.8 million available for future sale of common stock pursuant to the AGP ATM.

Note 6. Commitments and Contingencies

Contractual Obligations

The Company has commitments of approximately $230,000 as of March 31, 2025 over the next five years for several licensing agreements with partners and universities. Additionally, the Company is party to other agreements which include cash milestone payments, royalties and other fees payable, which are all contingent upon clinical or commercialization success. There can be no assurance that clinical or commercialization success will occur.

The Company currently leases office space pursuant to a lease which expires in October 2025. The current rent is $11,625 per month. The Company is currently in the process of negotiating the lease renewal.

In September 2014, the Company entered into an asset purchase agreement with Hy Biopharma Inc. ("Hy Biopharma") pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, the Company paid $275,000 in cash and issued 771 shares of common stock with a fair value based on the Company's stock price on the date of grant of $3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company's research and development activities and do not have alternative future use.

In March 2020, the Company filed a prospectus supplement covering the offer and sale of up to 8,151 shares of its common stock which were issued to Hy Biopharma as payment for achieving a milestone: the Company determining the Phase 3 clinical trial of HyBryte™ to be successful in the treatment of CTCL. The number of shares of common stock issued to Hy Biopharma was calculated using an effective price of $614.40 per share, based upon a formula set forth in the purchase agreement.

Provided the sole remaining future success-oriented milestone of FDA approval is attained, the Company will be required to make an additional payment of $5 million, if and when achieved. Such payment will be payable in restricted securities of the Company provided such number of shares does not exceed 19.9% ownership of the Company's outstanding stock. As of March 31, 2025, no other milestone or royalty payments have been paid or accrued.

In May 2025, the Company entered into an amendment to Dr. Schaber's employment agreement to increase the number of shares of common stock, from 2,084 to 200,000, issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party.

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

Year	Research and Development	Leases	Total
2025	$ 46,000	$ 81,375	$ 127,375
2026	46,000	—	46,000
2027	46,000	—	46,000
2028	46,000	—	46,000
2029	46,000	—	46,000
Total	$ 230,000	$ 81,375	$ 311,375

Note 7. Operating Segments

The Company operates in two reportable segments:

- Specialized BioTherapeutics – Focuses on developing and commercializing products for orphan diseases and areas of unmet medical need in oncology and inflammation.
- Public Health Solutions – Concentrates on vaccines and therapeutics for biodefense and infectious diseases.

The Company's CODM evaluates segment performance and allocates resources primarily based on the ability of the Specialized BioTherapeutics segment to advance its product development pipeline through a combination of government grants and contracts as well as shareholder investment. This segment represents the Company's primary focus and strategic priority.

In contrast, the Public Health Solutions segment is fully funded by government sources, with no investor capital used. The ability of this segment to secure government grants and contracts is a key determinant of its sustainability and its contribution to the Company's overall financial position. Funding from Public Health Solutions enables the Company to cover employee salaries, allocate funds to certain overhead costs such as rent and utilities, and supplement working capital.

Secondary to this, the CODM considers Adjusted Loss from Operations, which excludes non-cash share-based compensation and depreciation/amortization from operating expenses (R&D and G&A), and Net Loss Before Income Taxes, which incorporates these costs along with other income and expenses.

Segment Revenues and Profit (Loss)

The following table presents the revenues, significant expenses, and operating results of the Company's reportable segments for the three months ended March 31, 2025:

	Specialized BioTherapeutics	Public Health Solutions	Total Segments	Adjustments	Corporate	Adjustments	Consolidated
Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Cost of revenues	-	-	-	-	-	-	-
Gross profit	-	-	-	-	-	-	-
Significant expenses:							
Research and development	2,036,097	58,335	2,094,432	27,753	104,990	-	2,227,175
General and administrative	-	-	-	-	1,048,374	36,454	1,084,828
Adjusted loss from operations	(2,036,097)	(58,335)	(2,094,432)	(27,753)	(1,153,364)	(36,454)	(3,312,003)
Share-based compensation	26,488	840	27,328	(27,328)	36,271	(36,271)	-
Depreciation and amortization	364	61	425	(425)	183	(183)	-
Loss from operations	(2,062,949)	(59,236)	(2,122,185)	-	(1,189,818)	-	(3,312,003)
Other (expenses) income, net	-	-	-	-	75,240	-	75,240
Net loss before income taxes	$ (2,062,949)	$ (59,236)	$ (2,122,185)	$ -	$ (1,114,578)	$ -	$ (3,236,763)

The following table presents the revenues, significant expenses, and operating results of the Company's reportable segments for the three months ended March 31, 2024:

	Specialized BioTherapeutics	Public Health Solutions	Total Segments	Adjustments	Corporate	Adjustments	Consolidated
Revenues	$ 117,029	$ -	$ 117,029	$ -	$ -	$ -	$ 117,029
Cost of revenues	(117,029)	-	(117,029)	-	-	-	(117,029)
Gross profit	-	-	-	-	-	-	-
Significant expenses:							
Research and development	838,979	45,250	884,229	22,372	188,439	-	1,095,040
General and administrative	-	-	-		982,874	39,177	1,022,051
Adjusted loss from operations	(838,979)	(45,250)	(884,229)	(22,372)	(1,171,313)	(39,177)	(2,117,091)
Share-based compensation	20,672	588	21,260	(21,260)	38,701	(38,701)	-
Depreciation and amortization	953	159	1,112	(1,112)	476	(476)	-
Loss from operations	(860,604)	(45,997)	(906,601)	-	(1,210,490)	-	(2,117,091)
Other (expenses) income, net	7,540	-	7,540	-	194,224	-	201,764
Net loss before income taxes	$ (853,064)	$ (45,997)	$ (899,061)	$ -	$ (1,016,266)	$ -	$ (1,915,327)

The following table provides a reconciliation of total segment loss to consolidated loss before income taxes for the three months ended March 31:

	2025	2024
Loss from operations - reportable segments	**$ (2,122,185)**	$ (906,601)
Loss from operations - corporate	**(1,189,818)**	(1,210,490)
Interest income (expense), net	**76,028**	28,842
Other income (expense), net	**(788)**	172,922
Net loss before income taxes	**$ (3,236,763)**	$ (1,915,327)

Segment Assets

The Company's total assets by segment as of March 31, 2025, are presented below:

	Specialized BioTherapeutics	Public Health Solutions	Total Segments	Corporate	Consolidated
Total assets	**$ 110,793**	**$ 1,835**	**$ 112,628**	**$ 7,633,492**	**$ 7,746,120**

The Company's total assets by segment as of March 31, 2024, are presented below:

	Specialized BioTherapeutics	Public Health Solutions	Total Segments	Corporate	Consolidated
Total assets	$ 301,709	$ 120,475	$ 422,184	$ 7,636,201	$ 8,058,385

Significant Expense Categories Considered by CODM

The CODM regularly reviews the following significant expense categories when assessing segment performance and resource allocation:

- Government Grant and Contract Funding – Both the Specialized BioTherapeutics and Public Health Solutions segments apply for and receive government grants and contracts. However, Public Health Solutions is exclusively funded by government sources, whereas Specialized BioTherapeutics utilizes a mix of government funding and shareholder investment.
- Research & Development – Includes expenses for clinical trials, regulatory compliance, and R&D-related payroll.
- General & Administrative – Comprises salaries, professional fees, and facility costs.
- Share-Based Compensation – Represents non-cash stock option and restricted stock unit expenses.
- Depreciation & Amortization – Costs related to the use of tangible and intangible assets.
- Other Income/Expenses – Includes interest income and one-time gains/losses.

Chief Operating Decision Maker and Use of Multiple Measures of Segment Profit/Loss

The Company's CODM primarily evaluates segment performance based on two key financial measures:

- Advancement of Specialized BioTherapeutics Through a Combination of Funding Sources – Assesses the effectiveness of shareholder investment and government grants in progressing product development.
- Ability to Secure Government Grants and Contracts (Public Health Solutions Only) – Determines segment sustainability and funding for shared resources.
- Adjusted Loss from Operations – Excludes non-cash share-based compensation and depreciation/amortization expenses for a clearer picture of operating performance.
- Net Loss Before Income Taxes – Incorporates all expenses, including non-cash charges and other income/expenses, for a comprehensive profitability analysis.

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, 2024. 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 The Nasdaq Capital Market and meet its listing requirements;*
- *that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;*
- *maintenance and progression of our business strategy;*
- *the possibility that our products under development may not gain market acceptance;*
- *our expectations about the potential market sizes and market participation potential for our product candidates may not be realized;*
- *our expected revenues (including sales, milestone payments and royalty revenues) from our product candidates and any related commercial agreements of ours may not be realized;*

- *the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to timely address any regulatory issues that have arisen or may arise in the future;*

- *competition existing today or that may arise in the future, including the possibility that others may develop technologies or products superior to our products;*

- *the effect that global pathogens could have on financial markets, materials sourcing, service providers, patients, clinical study sites, governments and population (e.g. Coronavirus Disease 2019 ("COVID-19")); 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, 2024.*

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.

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.

Specialized BioTherapeutics

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 successful completion of the first Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study and 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 began patient enrollment during December 2024 for the second Phase 3 study called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2). We anticipate top-line results in the second half of 2026. Upon successful completion of the Phase 3 FLASH2 study, regulatory approval will be sought to support potential commercialization worldwide.

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

Public Health Solutions

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

Institute of Allergy and Infectious Diseases (“NIAID”), the Biomedical Advanced Research and Development Authority, and the Defense Threat Reduction Agency.

Business Strategy Overview

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 clinical trial of HyBryte™ in CTCL and positive primary endpoint results from the first Phase 3 FLASH study, continue enrollment and execution of 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.

- Expand 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 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.

- Expand development of dusquetide under the research name SGX945 into BD by conducting 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 United States (“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); new drug application ("NDA') submitted to FDA December 2022; FDA refusal to file ("RTF") letter received February 2023; second Phase 3 trial based upon EMA-accepted protocol began patient enrollment in December 2024 with top-line results anticipated in the second half of 2026; discussions continue with FDA on modifying the development path to adequately address FDA's preference for a longer duration comparative study over a placebo-controlled trial
SGX302	Mild-to-Moderate Psoriasis	Positive proof-of-concept demonstrated in a small Phase 1/2 pilot study; Phase 2a protocol and Investigation New Drug ("IND") clearance received from the FDA; Phase 2a study remains ongoing having demonstrated biological effect in Cohort 1 and clinically meaningful benefit in Cohort 2
SGX942†	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial results announced December 2020: the primary endpoint of median duration of severe oral mucositis ("SOM") did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group; analyzed full dataset from Phase 3 study and designing a second Phase 3 clinical trial; continued development contingent upon identification of partnership

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX945	Aphthous Ulcers in BD	Phase 2a protocol and Investigational New Drug ("IND") clearance received from the FDA; Phase 2a study initiated in 4Q 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 published Phase 3 study in CTCL has further confirmed the biological efficacy of synthetic hypericin (termed HyBryte™ in the context of CTCL). A confirmatory, placebo-controlled study based upon an EMA-accepted protocol is enrolling with top-line results expected in the 2nd half of 2026.

HyBryte™ – for Treating Cutaneous T-Cell Lymphoma

HyBryte™ is a novel, first-in-class, Photodynamic Therapy ("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.

Over the course of 2020, the Phase 3 FLASH study data was announced. 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) showed 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). The response rate in patients receiving a total of 12 weeks of 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). The data continued to indicate that HyBryte™ was safe and well tolerated.

Analysis of the optional third open-label treatment cycle (Cycle 3) 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. 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. We, the participating clinical investigators, and any other 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 an 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.

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.

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 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 refusal to file ("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, expected to enroll approximately 80 patients across the US and Europe, began patient enrollment in December 2024, with top-line results anticipated in the second half of 2026.

In September 2024, the European Patent Office granted the patent entitled "Systems and Methods for Producing Synthetic Hypericin". The newly issued patent's claims are directed to a novel, highly purified form of synthetic hypericin manufactured through a unique proprietary process. Synthetic hypericin is the active pharmaceutical ingredient in HyBryte™, our photodynamic therapy for the treatment of CTCL, set to initiate a confirmatory Phase 3 clinical trial before the end of the year. This new European granted patent (EP3423428) is a related patent to US Pat. No. 10,053,413, previously issued in the U.S. Both patents are expected to expire in 2036, and form part of a larger patent family, including previously granted U.S. patents covering methods of use (US Pat. No. 7,122,518) and methods of synthesis (US Pat. No. 8,629,302), as well as other granted patents throughout the world.

In October 2024, we established a partnership agreement with Sterling Pharma Solutions Limited (“Sterling”) to optimize and implement a commercially viable, scalable production technology for synthetic hypericin. We are currently working to transfer and optimize the manufacturing processes and analytics to enable GMP manufacturing for clinical trials with the intent of establishing a long-term commercial manufacturing collaboration.

In October 2024, the Hong Kong Patent Office granted the patent entitled "Systems and Methods for Producing Synthetic Hypericin". The newly issued patent's claims are directed to a novel, highly purified form of synthetic hypericin manufactured through a unique proprietary process. Synthetic hypericin is the active pharmaceutical ingredient in HyBryte™, our photodynamic therapy for the treatment of CTCL, for which a confirmatory Phase 3 clinical trial has been initiated. This new granted patent (HK1260757) is a related patent to US Pat. Nos. 10,053,413 and 10,526,268, previously issued in the U.S., and is in the same family as another patent granted in Europe. These patents are expected to expire in 2036, and form part of a larger collection of different patent families, including previously granted foreign patents covering liquid formulations and methods of use (EP Pat. No. 2,571,507) and issued U.S. patents for methods of synthesis (US Pat. No. 8,629,302), as well as other granted patents throughout the world.

In December 2024, we announced positive clinical results from a comparability study evaluating HyBryte™ versus Valchlor® (mechlorethamine gel) in the treatment of early-stage CTCL. The open-label study has demonstrated continued improvement in HyBryte™ treated patients and their individual lesions even after stopping treatment. The study, which enrolled 10 patients randomized 1:1 with 12 weeks of treatment and 4 weeks of follow-up post-treatment, was previously reported to demonstrate a positive difference in the overall per patient treatment response rate (60% in the HyBryte™ group vs. 20% in the Valchlor® group) at the end of treatment. After the 4-week follow-up period (Week 16), the majority (3 of 5) of HyBryte™ patients continued to demonstrate improvement with at least a further 10% improvement (absolute difference) at Week 16 relative to the primary outcome measure at Week 12, including one of the HyBryte™ patients achieving a "complete response". In contrast, of the four patients that completed the Valchlor® arm of the study, none achieved this level of improvement by Week 16. For patients, a treatment response was defined as a ≥50% improvement in their cumulative mCAILS score over 3 to 5 lesions. Treatment response was also assessed on individual lesions. There was a similar continued improvement in the lesion responses over time, with the plaque lesions of particular interest given their increasing association with risk of overall disease progression and long-term mortality. At the 12-week (end of treatment) timepoint, the HyBryte™ treated plaque lesions were statistically significantly improved compared to the Valchlor® treated plaques (63%, [10/16] treatment success with HyBryte™ vs. 17%, [2/12] with Valchlor®, p=0.02). By Week 16, the response rates in lesions treated with HyBryte™ were statistically significant responses for all lesions (72% HyBryte™ vs 28% Valchlor®, p=0.02) and specifically for plaque lesions (75% responding plaque lesions with HyBryte™ treatment vs. 17% with Valchlor®, p=0.006) relative to the Valchlor® group. No safety concerns with HyBryte™ were raised during the follow-up period.

In December 2024, we opened patient enrollment for our confirmatory Phase 3 study evaluating HyBryte™ (synthetic hypericin) in the treatment of CTCL.

In April 2025, we announced interim results from the ongoing open-label, IIS evaluating extended HyBryte™ treatment for up to 54 weeks in patients with early-stage CTCL. Following 18 weeks of treatment, 75% of patients achieved "Treatment Success," reinforcing HyBryte™ as a potentially safe and fast-acting therapy for this chronic and underserved cancer. To date, nine patients have been enrolled and treated with HyBryte™ over a time period of up to 54 weeks in the IIS, with all data for the Week 18 timepoint now complete. Consistent with the Phase 3 trials, Treatment Success is predefined as a greater than or equal to 50% improvement in the cumulative mCAILS score compared to Baseline. Of the eight patients who could be evaluated through Week 18, six (75%) had a Treatment Success. The 18-week treatment window is the same window that is being evaluated in the FLASH2 double-blind, placebo-controlled, randomized study that is currently enrolling patients. This rapid response is a distinct advantage of HyBryte™ therapy, with many other therapies used in CTCL taking up to six to 12 months to generate a clinically meaningful treatment response. Of these eight evaluable patients through Week 18, four have gone on to complete the 54-week treatment with an average maximum improvement in mCAILS score of 85%, three are still on treatment and one dropped out (due to logistical issues). HyBryte™ appears to be safe and well tolerated in all patients. The trial is sponsored by Ellen Kim, MD, Director, Penn Cutaneous Lymphoma Program, Vice Chair of Clinical Operations, Dermatology Department, and Professor of Dermatology at the Hospital of the University of Pennsylvania who was a leading enroller in the Phase 3 FLASH study for the treatment of early-stage CTCL.

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. CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to 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). We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the U.S., with approximately 2,800 new cases seen 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 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.

In a 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, we conducted a Phase 3 clinical trial referred to as the “DOM–INNATE” (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) study. The Phase 3 protocol was a 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.

The results of the study 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 BD. BD 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 BD 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 BD 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 BD.

In November 2024, we opened patient enrollment for the Phase 2 study (protocol number DUS-AUBD-01) evaluating SGX945 (dusquetide) in the treatment of BD.

We estimate the potential worldwide market for SGX945 is in excess of $200 million for the treatment of aphthous ulcers in BD. 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

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 over 50,000 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 a previous $9.4 million NIAID grant which enabled 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 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.

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.

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.

In March 2025, we announced a publication describing the preclinical efficacy of CiVax™, a thermostabilized subunit vaccine against SARS-CoV-2. Using custom-developed immunoassays, the combination of a primary adenovirus vaccine (COVID-19 Vaccine AstraZeneca) coupled with a CiVax™ booster was shown to induce broader protection against COVID-19 variants in non-human primates than a 2-shot mRNA series (such as the Moderna vaccine Spikefax® or the Pfizer vaccine Cominarty®) in humans. In collaboration with Axel Lehrer, PhD, Professor at the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Mānoa, the manuscript entitled *"Use of a Multiplex Immunoassay Platform to Investigate Multifaceted Antibody Responses in SARS-CoV-2 Vaccinees with and Without Prior Infection"*, has been published in COVID.

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. No funds are remaining from any of these grants.

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.

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.

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 (approximately $2.5 million for fiscal year 2025).

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 ("WMD") 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.

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 the accompanying 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. Actual results may differ from these estimates under different assumptions or conditions.

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.

Material Changes in Results of Operations

Three Months Ended March 31, 2025 Compared to March 31, 2024

For the three months ended March 31, 2025, we had a net loss of $3,236,763 as compared to a net loss of $1,915,327 for the same prior year period, representing increased net loss of $1,321,436. This increase in net loss was primarily due to an increase in operating expenses related to ongoing clinical trials and a decrease in other income which was attributable to the change in the fair value of debt during the three months ended March 31, 2024 with no corresponding change in fair value during the three months ended March 31, 2025.

Our revenues and associated costs incurred related to government subawards received to support the evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL. For the three months ended March 31, 2025 we had no revenue as compared to revenue of $117,029 for the same prior year period, representing a decrease of $117,029. We also incurred costs related to those revenues for the three months ended March 31, 2024 of $117,029.

Research and development expenses were $2,227,175 for the three months ended March 31, 2025 as compared to $1,095,040 for the same period in 2024, representing an increase of $1,132,135. The increase was primarily due to costs associated with our Phase 2 study in BD and the second confirmatory Phase 3 CTCL trial as well as increases in third party manufacturing.

General and administrative expenses were $1,084,828 for the three months ended March 31, 2025, as compared to $1,022,051 for the same period in 2024, representing an increase of $62,777. The increase in general and administrative expenses for the three months ended March 31, 2025 was primarily attributable to increases in professional fees and various taxes.

We recognized $165,382 of other income from the change in the fair value of convertible debt on our accompanying condensed consolidated statements of operations during the three months ended March 31, 2024. The convertible debt was fully repaid in February 2025.

Interest income, net for the three months ended March 31, 2025 was $76,028 as compared to $28,842 for the same period in 2024, representing an increase of $47,186. The increase is primarily associated with a reduction in interest expense resulting from repayment of convertible debt.

Financial Condition

Cash and Working Capital

As of March 31, 2025, we had cash and cash equivalents of $7,297,171 as compared to $7,819,514 as of December 31, 2024, representing a decrease of $522,343. As of March 31, 2025, we had working capital of $3,507,060 as compared to working capital of $3,980,218 as of December 31, 2024, representing a decrease of $473,158. The decrease in cash and cash equivalents was primarily related to cash used in operating activities and repayment of convertible debt offset by cash received from financing activities during the three months ended March 31, 2025.

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 to support development activities, business operations, and meet our obligations through the fourth quarter of 2025. However, as of the date of filing this Quarterly Report on Form 10-Q, we do not have sufficient cash and cash equivalents to fund operations for at least 12 months following the issuance of these financial statements. These factors raise substantial doubt about our ability to continue as a going concern.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, our plans include securing:

- additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations.

- additional proceeds from government contract and grant programs.

- additional proceeds from the sale of shares of our common stock via the At Market Issuance Sales Agreement ("AGP Sales Agreement") with A.G.P/Alliance Global Partners ("AGP").

Other than the AGP Sales Agreement, which was entered into on August 16, 2024, none of these alternatives are currently committed. There is no assurance that we will obtain sufficient funding on acceptable terms, if at all, to continue operations, enter into strategic transactions that provide the necessary capital, or implement other strategies to mitigate the substantial doubt about our ability to continue as a going concern. If these alternatives are unavailable or not secured on satisfactory terms, we will not have sufficient cash resources or liquidity to fund our operations for at least 12 months after the financial statements are issued. Failure to obtain adequate capital when needed may force us to delay, reduce, or eliminate business development efforts, negatively impacting our ability to achieve our objectives, remain competitive, and maintain our financial condition and operating results. Additionally, market instability, including geopolitical factors, may limit our access to capital, further straining our liquidity and ability to continue as a going concern. The perception of financial instability may also deter potential business partners due to concerns about our ability to fulfill 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 $554,000 in active government grant funding still available as of March 31, 2025 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 will continue 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 have up to approximately $1.8 million remaining from the AGP Sales Agreement as of May 2, 2025 under the prospectus supplement updated August 16, 2024. From April 1, 2025 through May 2, 2025, we sold 80,354 shares of common stock pursuant to the AGP Sales Agreement at a weighted average price of $2.41 per share for total gross proceeds of approximately $194,000; 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.

Research and Development 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 million before any contract or grant reimbursements, all of which relates to the Specialized BioTherapeutics business segment. We do not anticipate any contract and grant reimbursements revenue in the next 12 months 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, 2025 and 2024:

	2025	2024
Research & Development Expenses		
RiVax® and ThermoVax® Vaccines	**$ 59,175**	$ 45,839
SGX942 (Dusquetide)	**74,061**	19,258
HyBryte™ (SGX301 or synthetic hypericin)	**1,988,525**	840,393
Other	**105,414**	189,550
Total	**$ 2,227,175**	$ 1,095,040
Reimbursed under Government Contracts and Grants		
HyBryte™ (investigator-initiated study)	**—**	117,029
Total	**—**	117,029
Grand Total	**$ 2,227,175**	$ 1,212,069

Contractual Obligations

We have commitments of approximately $230,000 as of March 31, 2025 over the next five years for several licensing agreements with partners and universities. Additionally, we are party to other agreements which include cash milestone payments, royalties and other fees payable, which are all contingent upon clinical or commercialization success. There can be no assurance that clinical or commercialization success will occur.

We currently lease office space pursuant to a lease which expires in October 2025. The current rent is $11,625 per month. We are currently in the process of negotiating the lease renewal.

In September 2014, we entered into an asset purchase agreement with Hy Biopharma Inc. (“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 paid $275,000 in cash and issued 771 shares of common stock with a fair value based on 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.

In March 2020, we filed a prospectus supplement covering the offer and sale of up to 8,151 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 $614.40 per share, based upon a formula set forth in the asset purchase agreement.

Provided the sole remaining future success-oriented milestone of FDA approval is attained, we will be required to make an additional payment of $5 million, if and when achieved. Such payment will be payable in our restricted securities provided such number of shares does not exceed 19.9% ownership of our outstanding stock. As of March 31, 2025, no other milestone or royalty payments have been paid or accrued.

In May 2025, we entered into an amendment to Dr. Schaber's employment agreement to increase the number of shares of common stock, from 2,084 to 200,000, issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party.

In December 2020, we entered into a $20 million convertible debt financing agreement with Pontifax (the "Loan Agreement"). Under the terms of the Loan Agreement, 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 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 on 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 Loan Agreement (the "2023 Amendment"). The 2023 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 2023 Amendment also provided for interest only through June 30, 2024, reduced quarterly principal repayments to $750,000, and eliminated the minimum cash covenant. Further, the 2023 Amendment reduced the conversion price with respect to the remaining principal amount to (i) 90% of the closing price of our common stock on the day before the delivery of a conversion notice with respect to the first 36,790 shares of our common stock issuable upon conversion and to (ii) $27.20 with respect to all shares of our common stock issuable upon conversion thereafter. The remaining terms of the agreement remained unmodified.

On January 3, 2024, Pontifax delivered a conversion notice to us electing to convert a portion of the remaining principal balance into shares of our common stock. Upon conversion, we issued 9,139 shares of our common stock at $10.88 per share, reducing the remaining principal balance by $99,416.

On April 15, 2024, Pontifax delivered a conversion notice to us electing to convert a portion of the remaining principal balance into shares of our common stock. Upon conversion, we issued 27,651 shares of our common stock at $5.60 per share, reducing the remaining principal balance by $154,840.

The 2023 Amendment 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. As a result, we recognized $0 and $165,382 of other income from the change in the fair value of the convertible debt in our accompanying condensed consolidated statements of operations during the three months ended March 31, 2025 and 2024, respectively. The fair value of the convertible debt was estimated using the Monte Carlo valuation method.

In October 2024, we entered into an amendment (the "2024 Amendment") to the Loan Agreement, as amended. The 2024 Amendment reduced the conversion price with respect to the remaining principal amount outstanding to (i) $3.81 for the first 501,648 shares of our common stock issuable upon conversion and (ii) $4.23 with respect to all shares of our common stock issuable upon conversion thereafter. The remaining terms of the agreement remained in effect with minimal, non-material modifications to those terms.

In February 2025, we fully repaid all outstanding obligations and terminated the Loan Agreement. As a result, all related liens and security interests securing our obligations were released. We did not incur any prepayment penalties for the early repayment.

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, 2025, 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, 2025, 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, 2024. 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. Further, 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.

The following 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, 2024 and in our periodic reports on Form 10-Q and Form 8-K.

Risks Related to Our Securities

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

As of May 2, 2025, we had a number of agreements or obligations that may result in dilution to investors. These include:

- common stock warrants to purchase a total of 1,467,581 shares of our common stock at a current weighted average exercise price of $11.01;
- options to purchase approximately 92,691 shares of our common stock at a current weighted average exercise price of $47.73; and
- 5,770,122 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.

Risks Related to Marketing Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of our current or future product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities such as the EMA, which regulations differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of a biologics license application ("BLA"), NDA or marketing authorization from the FDA or marketing approval from applicable regulatory authorities outside the United States. Product candidates in the development phase are subject to the risks of failure inherent in drug development. We have not received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including third-party clinical research and regulatory consultants, to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

We will need to carefully review the guidance and advice that FDA and other regulatory and scientific authorities in foreign jurisdictions, including the Committee for Medicinal Products for Human Use ("CHMP"), provide in any meetings we have with those authorities to discuss our clinical development programs. Sponsors are given opportunities to meet with the FDA and other regulatory bodies at certain points in their development programs. At the conclusion of these meetings, the FDA and comparable regulatory authorities provide responses to questions posed by the sponsor regarding the clinical development program. They will not indicate whether an application will be approved, but will provide guidance to the sponsor on various questions, including what types of studies and data are likely necessary to support review and potential approval of an NDA, BLA or marketing authorization. For example, the FDA may express support for the sponsor's approach in the clinical development program but indicate that questions concerning whether the data support approval will be subject to review by the agency following its acceptance for filing of the NDA or BLA. While such guidance is not legally binding, our failure to carefully consider these recommendations for the design of a clinical program may put the program at significant risk of failure.

Further, the FDA or other comparable foreign regulatory authorities may determine that we must provide additional evidence of safety or efficacy before approving a BLA, NDA or marketing authorization for our product candidates. For example, the FDA reviews an application to determine whether there is "substantial evidence" to support a finding of efficacy for the proposed product for its intended use(s). The FDA has interpreted this evidentiary standard to generally require at least two adequate and well-controlled clinical trials to establish efficacy of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional confirmatory evidence may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate efficacy. In the event that we submit a BLA, NDA or marketing authorization on the basis of one clinical trial and confirmatory evidence, the FDA or other comparable foreign regulatory authorities could determine that such information is not sufficient to support approval of the application and the agencies could require us to conduct an additional trial in support of the BLA, NDA or marketing authorization. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU member state will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU member states and the public. If we seek approval of our clinical trials in the EU pursuant to this regulation, there can be no assurance that we will be able to secure such an authorization for our product candidates.

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

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Further, under the Pediatric Research Equity Act, an NDA or BLA, or supplement to an NDA or BLA, for certain drugs and biological products must contain data to assess the safety and efficacy of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or efficacy data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking marketing approval in the United States or the Europe, we cannot guarantee that we will be able to obtain a

waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the EU and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain U.S. approval. The marketing approval process outside the United States generally includes similar risks as associated with obtaining FDA approval. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-United States marketing approvals and compliance with non-United States regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-United States approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-United States regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the UK as a result of the withdrawal of the UK from the EU, commonly referred to as “Brexit.” The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the MHRA, is responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure (“IPR”) will apply, which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators (“RRs”). The RRs notably include the EMA and regulators in the EU/European Economic Area (“EEA”), member states for approvals in the EU centralized procedure and mutual recognition procedure, as well as the FDA (for product approvals granted in the U.S.). Any delay in obtaining, or an inability to obtain, any approvals may force us or our collaborators to restrict or delay efforts to seek marketing approval in the UK for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission’s proposal for revision of several legislative instruments related to medicinal products (among other things, potentially reducing the duration of regulatory data protection and revising the eligibility for expedited pathways) was published in April 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore

be substantially revised before adoption, which is not anticipated before 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets (such as the war between Ukraine and Russia and the conflict in the Middle East); compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We, or any future collaborators, may not be able to obtain or maintain orphan drug designation or orphan drug exclusivity for any future product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We, or any future collaborators, may seek orphan drug designations and may be unable to obtain such designations. Certain of our current product candidates have been granted orphan drug designation by the FDA and orphan medicinal product designation by the EMA.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because the FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

FDA, congressional or judicial action may further effect the application the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA or Congress may change, or courts may interpret, the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes are made to orphan drug regulations and policies or how such regulations or polices are interpreted, our business could be adversely impacted.

In addition, to obtain and maintain orphan drug designation in the EU, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the medicinal product will be of substantial benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for any product candidate.

Any product candidate for which we obtain marketing approval would remain subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices ("cGMP") requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a REMS. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any product candidate for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with applicable laws.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward

the prescribers of drugs and/or the general public, are strictly regulated in the EU and are also subject to EU member state laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, our or any future collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Regenerative Medicine Advanced Therapy ("RMAT"), Fast Track and Priority Review designations in the United States, and the PRIority Medicines ("PRIME") designation in the EU, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy and RMAT product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough and RMAT therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a Priority Review designation for one or more of our product candidates. If the FDA determines that a product candidate would provide a significant improvement in safety or efficacy, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Further, obtaining any of these designations does not assure or increase the likelihood of the marketing approval by the FDA.

In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists,

it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may seek approval of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated development pathways. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay or prevent the receipt of, necessary marketing approvals. Moreover, even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional NDAs or BLAs seeking accelerated approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval. Furthermore, for any submission of an application for accelerated approval, there can be no assurance that such submission will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all. Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions, that govern accelerated approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek a priority review voucher ("PRV"), for our current and future product candidates. A BLA or NDA for our current and future product candidates will not, however, meet the eligibility criteria for a PRV, unless we secure the applicable designation and approval of the BLA or NDA for the product candidate.

Congress has authorized the FDA to award PRVs to sponsors of certain drugs for tropical diseases or rare pediatric diseases or to use as medical countermeasures that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain tropical diseases, rare pediatric diseases and illnesses related to public health emergencies. Specifically, under this program, a sponsor who receives approval for a new drug or biologic for a tropical diseases, rare pediatric diseases or illnesses related to a public health emergency may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505(b)(1) of the FDCA or Section 351 of the Public Health Service Act as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file.

In order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the BLA or NDA must be for a product that does not include a previously approved active ingredient in addition to meeting other applicable requirements.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates, including drug substance, drug product and device combinations that may be used in combination with our product candidates, for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing.

We or our contract manufacturers must supply all necessary documentation in support of a BLA or NDA on a timely basis and must adhere to the FDA's current good laboratory practices and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our contract manufacturers. If any such inspection or audit identifies failure to comply with

applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility, which may lead to temporary or permanent supply shortages. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

Inadequate funding for the FDA, the SEC and other government agencies. Including from government shutdowns competing priorities or other disruptions to these agencies' operations, and regulatory reform efforts, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies, including government agencies and regulatory authorities outside the United States, on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Further, while the FDA's review of NDAs and BLAs is funded by the user fee program established under the Prescription Drug User Fee Act ("PDUFA"), the Trump Administration has indicated that it will be reviewing that program and its implementation.

In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Disruptions or competing priorities at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our product candidates that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

We expect that recent healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. There have been several Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing

approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

The insurance coverage and reimbursement status of newly approved products is uncertain. Our product candidates, if approved, may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for any of our product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs and other medical products vary widely from country to country. In the United States, healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our products and product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Sales of any product we successfully develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels or only after clearing significant barriers, such as the requirement to fail on other products before providing reimbursement, we may not be able to successfully commercialize any product we may successfully develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for any product we may successfully develop. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare and Medicaid Services (“CMS”). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for

products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of any product we may successfully develop to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In the Europe and in the rest of the world, pricing and reimbursement schemes vary widely from country to country and may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

Further, some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Finally, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We may experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we

market, sell and distribute any products for which we obtain marketing approval. Potentially applicable United States federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Department of Health and Human Services ("HHS") information related to physician and healthcare provider payments and other transfers of value and physician ownership and investment interests.

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, corporate integrity or other similar forms of agreements or decrees, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, EU and the UK. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information that may impact certain of our business operations. For example, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical, and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity, and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. Enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition to potential enforcement by the HHS, we could also be potentially subject to privacy enforcement from the Federal Trade Commission (the “FTC”). The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC’s evolving rules and guidance for proper privacy and data security practices in

order to mitigate risk for a potential enforcement action, which may be costly. Finally, both the FTC and HHS's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the U.S. to certain foreign countries. Failure to comply with these rules can lead to a potential FTC enforcement action. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

There also are state privacy and security laws that also may be applicable to our business activities now or in the future. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries which we will need to navigate.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We are subject to United States and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the Foreign Corrupt Practices Act, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement

actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU member states and the U.K. Bribery Act 2010. Violations of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws

and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On March 14, 2025, we issued a vendor 12,346 shares of common stock with a fair value of $2.43 per share. Such issuance was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended. The recipient is knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about us or had adequate access to information about us. The vendor represented to us that the vendor is not a “consultant” for purposes of Nasdaq Listing Rule 5635(c).

ITEM 5 – OTHER INFORMATION

On May 5, 2025, we entered into an amendment (the “Amendment”) to our employment agreement with Christopher J. Schaber, PhD, our President and Chief Executive Officer. Pursuant to the Amendment, we increased, from 2,084 shares to 200,000 shares, the number of shares of common stock that we would issue to Dr. Schaber prior to the completion of a transaction, or series or combination of related transactions, negotiated by our Board of Directors whereby a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party. The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

During the quarter ended March 31, 2025, 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
10.1	Fourth Amendment to Employment Agreement dated as of May 5, 2025, between Soligenix, Inc. and Christopher J. Schaber, PhD.
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 9, 2025

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

May 9, 2025

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

EXHIBIT 10.1

FOURTH AMENDMENT
TO
EMPLOYMENT AGREEMENT

This Fourth Amendment to Employment Agreement (the "Amendment") is made and entered into as of May 5, 2025 by and between Soligenix, Inc., a Delaware corporation having a place of business at 29 Emmons Drive, Suite B-10, Princeton, NJ 08540 (the "Corporation"), and Christopher J. Schaber, Ph.D. (the "Employee").

RECITALS

WHEREAS, the Corporation and the Employee are parties to that certain Employment Agreement dated December 27, 2007, as amended by that certain First Amendment to Employment Agreement dated July 12, 2011, that certain Second Amendment to Employment Agreement dated January 2, 2020, that certain Third Amendment to Employment Agreement dated December 10, 2020 (as amended, the "Employment Agreement"), pursuant to which the Corporation employs the Employee as President and Chief Executive Officer; and

WHEREAS, the Corporation and the Employee desire to further amend the Employment Agreement in accordance with the terms thereof and upon the terms set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Corporation and the Employee hereby agree as follows:

AMENDMENT OF EMPLOYMENT AGREEMENT

1. Section 3(c) of the Employment Agreement is hereby amended and restated in its entirety as follows:

> (c) 200,000 shares of common stock of the Corporation will be issued to Employee immediately prior to the completion of a transaction, or series or combination of related transactions, negotiated by the Corporation's Board of Directors whereby, directly or indirectly, a majority of the Corporation's capital stock or a majority of its assets are transferred from the Corporation and/or the Corporation's stockholders to a third party.

OTHER PROVISIONS INCORPORATED AND UNCHANGED

All other provisions of the Employment Agreement are incorporated herein and shall remain in full force and effect, including, but not limited to, capitalized terms that are not otherwise defined herein.

EFFECT OF AMENDMENT

The amendments to the Employment Agreement made hereby shall be effective as of the date hereof.

ENTIRE AGREEMENT MODIFICATION

The Employment Agreement, as amended hereby, contains the entire agreement of the parties relating to the subject matter hereof, and the parties hereto have made no agreements, representations or warranties relating to the subject matter hereof which are not set forth herein. No modification hereof shall be valid unless made in writing and signed by the parties hereto.

GOVERNING LAW

This Amendment shall be governed by, and construed and interpreted in accordance with, the laws of the State of New Jersey without regard to principles of conflict of laws.

COUNTERPARTS

This Amendment may be executed in counterparts, each of which shall, when executed and delivered, constitute an original of this Amendment, but all of which shall together constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any other electronic signature, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

{signature page follows}

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the day and year above written.

SOLIGENIX, INC.

By: */s/ Jonathan L. Guarino*
Jonathan L. Guarino, CPA
Chief Financial Officer, Senior Vice President, and Corporate Secretary

EMPLOYEE:

By: */s/ Christopher J. Schaber*
Christopher J. Schaber, PhD

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, 2025;

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 9, 2025

/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, 2025;

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 9, 2025

/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, 2025, 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 9, 2025

/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, 2025, 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 9, 2025

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