SOLIGENIX

Soligenix, Inc.
29 Emmons Drive Suite B-10
Princeton, NJ 08540

Phone: 609.538.8200
Fax: 609.452.6467

January 10, 2022

Dear Friends and Shareholders,

I would like to start by thanking you for your continued support, and hope that you and your families had a healthy and happy holiday season. As we look ahead to 2022, we remain energized by the promise of our development pipeline as we continue to evaluate potential strategic options, including, but not limited to, partnership and merger and acquisition opportunities. The previously publicly disclosed upcoming key events and milestones for the year can be summarized as follows:

- submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing authorization of HyBryte™ (SGX301 or synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL);
- initiation of a Phase 2 clinical trial in mild-to-moderate psoriasis with SGX302 (synthetic hypericin), where we have already validated the biologic activity of synthetic hypericin in CTCL and previously demonstrated positive proof of concept (PoC) in a small Phase 1/2 pilot study in psoriasis;
- pursuit of potential opportunities with dusquetide, the active ingredient in SGX942 that demonstrated biological efficacy in the per protocol population in our Phase 3 clinical study in oral mucositis in head and neck cancer (HNC), and potential anti-tumor efficacy in multiple preclinical xenograft studies;
- advancing our heat stable vaccine platform technology, including development of filovirus vaccine candidates (targeting Ebola, Sudan, and Marburg Viruses), a novel heat stable COVID-19 (Coronavirus Disease 2019) vaccine candidate, CiVax™, and a ricin toxin vaccine, RiVax®, where non-human primate (NHP) data for all three vaccine programs has demonstrated significant efficacy; and
- a final decision rendered from our arbitration with Emergent BioSolutions, Inc. and certain of its subsidiaries, where we are seeking to recover damages from Emergent regarding alleged issues experienced with the manufacture of the RiVax® active ingredient at their contract facilities.

Additionally, we continue to follow through on our financing strategies, providing us with sufficient capital and cash runway to meet our goals into 2023 as we move towards U.S. commercialization of HyBryte™ in CTCL. We expect peak annual net sales of HyBryte™ in the

U.S. to exceed $90 million, with the total addressable worldwide CTCL market estimated at approximately $250 million annually. Preliminary analysis of the total addressable worldwide psoriasis market opportunity with SGX302, which uses the same active ingredient as HyBryte™, is significant and estimated to exceed $1 billion annually. Overall, we are excited about our near-term and future upcoming catalytic milestones.

Corporate Highlights

Since our last update, we have continued to advance our development programs across both the Specialized BioTherapeutics and Public Health Solutions business segments of our rare disease pipeline, *where we currently anticipate achieving multiple important and potentially transformational milestones through 2023*. We also continue to evaluate strategic options before us to better position the company for potential success. A more detailed review of the business is provided below.

Specialized Biotherapeutics Business Segment

At the end of 2020, we were very happy to announce completion of our pivotal Phase 3 FLASH ("Fluorescent Light Activated Synthetic Hypericin") study with HyBryte™ and share the continued positive benefits for our CTCL patients. Compared to the currently approved CTCL therapies for early disease, the treatment response to HyBryte™ was very rapid, being detected in as little as 6 weeks of treatment (Cycle 1, $p=0.04$). Responses continued to improve through 12 weeks of treatment (Cycle 2, $p<0.0001$ vs end Cycle 1) and 18 weeks of treatment (Cycle 3, $p<0.0001$ vs end Cycle 1), ultimately enabling nearly half of patients who continued treatment to see sustained and significant improvement in their response rates. Durability of response also was increased following more treatment. HyBryte™ also demonstrated statistically significant responses in both patch (Cycle 2 response 37%, $p=0.0009$) and thicker plaque (Cycle 2 response 42%, $p<0.0001$) lesions, highlighting the unique benefits of the more deeply penetrating visible light activation of hypericin. Importantly, treatment response was found to be very good in patients receiving HyBryte™ as their first CTCL therapy as well as those that had been treated with multiple prior therapies for their CTCL, indicating the broad applicability of HyBryte™ for patients inflicted with this chronic cancer. Unlike second-line and off-label therapies for CTCL, HyBryte™ was better tolerated with a reduced dropout rate and more broadly effective, with equal efficacy against both plaque and patch lesions. Further, no synthetic hypericin was detected in the bloodstream of patients, minimizing safety concerns of drug effects outside of the tumor area. With the long-term follow-up visits now completed, the overall tolerability of treatment has been further confirmed and the full data set is being incorporated into the NDA filing.

As Brian Poligone, MD, PhD, Lead Enrolling Investigator in the FLASH study and Director of the Rochester Skin Lymphoma Medical Group, Fairport, NY, USA has stated, "Along with HyBryte™'s rapid response time and safety profile, the patch and plaque data from the study are extremely compelling. Current treatments for CTCL are generally less effective against plaques and deeper lesions, very similar to the problem observed in psoriasis. These results are consistent with the positive findings highlighted in a recently reported case study of folliculotropic mycosis fungoides, a hard to treat variant of CTCL where lesions are associated with the hair follicles deep in the skin and more resistant to phototherapy."

In mid-2021, Ellen Kim, MD, Medical Director, Dermatology Clinic, Perelman Center for Advanced Medicine, Professor of Dermatology at the Hospital of the University of Pennsylvania, and the Lead Principal Investigator for the Phase 3 FLASH study in CTCL, presented key details of HyBryte™'s broad efficacy and safety demonstrated in the FLASH study at multiple prominent scientific congresses, which included the American Academy of Dermatology, the Society of Investigative Dermatology and the U.S. Cutaneous Lymphoma Consortium. Additional data from the Phase 3 FLASH study also was presented at the 2021 National Organization for Rare Disorders (NORD) Breakthrough Summit. Key highlights of note from the presentations included:

- HyBryte™ is activated by visible light at a wavelength of 500-650 nm, which provides deeper dermal penetration than ultraviolet (UV) spectrum light. This resulted in statistically significant clinical responses observed in patches as well as deeper plaque lesions, which are typically more difficult to treat and generally less responsive to UV light therapy.
- In addition to its demonstrated, statistically significant efficacy which ultimately led to 49% of patients achieving at least a 50% reduction in their lesions (graded using a standard measurement of CTCL lesions, the CAILS score) after 18 weeks of therapy ($p<0.0001$), complete responses of all treated index lesions also were shown to occur. These complete responses increased in frequency as treatment with HyBryte™ continued and photographs demonstrating this response were reviewed.
- Treatment response was similar across all patient subgroups, including those with Stage IA or Stage IB disease and those taking <2 or ≥ 2 therapies prior to starting the HyBryte™ trial.
- Compared to second-line approved drugs for the treatment of CTCL, HyBryte™ demonstrated significantly fewer safety concerns. This was reflected in the low rate of study discontinuation attributed to adverse events which showed only a 5% overall drop-out rate during the treatment phase in HyBryte™ treated patients, lower than typically observed in other early stage CTCL trials.

"This trial was the largest multicenter, randomized, double-blind, placebo-controlled skin directed therapy study in MF/CTCL (mycosis fungoides/cutaneous T-cell lymphoma) to date," noted Dr. Kim in a recent interview. "It is so exciting to be able to tell the world about the efficacy and safety we saw HyBryte™ demonstrate in this trial. Based on its non-mutagenic mechanism of action, HyBryte™ should not be associated with long-term actinic skin damage or increased risk of skin cancer, which would be an advantage over traditional UV light-based phototherapy."

With the study complete, we now are focused on preparing to *submit the NDA in the second half of 2022* for this first-in-class therapy. HyBryte™ has received Orphan Drug and Fast Track designations from the FDA. Additionally, HyBryte™ was granted Orphan Drug designation from the European Medicines Agency (EMA), as well as a Pediatric Investigation Plan (PIP) waiver from the EMA. In the United Kingdom (UK), HyBryte™ has been granted a PIP product-specific waiver as well as Promising Innovative Medicine designation from the Medicines and Healthcare products Regulatory Agency (MHRA), and more recently, was awarded an "Innovation Passport" for the treatment of early stage CTCL in adults under the UK's Innovative Licensing and Access Pathway (ILAP). ILAP was launched at the start of 2021 to accelerate the development and access to promising medicines, thereby facilitating patient access to new medicines. This pathway features enhanced input and interactions with the MHRA and other key stakeholders.

We announced a strategic partnership with Daavlin, a leading manufacturer of phototherapy devices used worldwide by dermatologists and patients, for supply and distribution of our HyBryte™ companion light device. This exclusive supply, distribution and services agreement with Daavlin will secure long-term supply and distribution of a commercially ready light device that is an integral component of the regulatory and commercial strategy for HyBryte™ for the treatment of CTCL. We held an investor webcast event in 2021 to discuss the unique U.S. commercialization opportunity for HyBryte™ in the treatment of CTCL. During that webcast, we reviewed in some detail the disease, competitive landscape, and our intent to commercialize HyBryte™ ourselves in a cost efficient and profitable manner. As CTCL is a highly specialized orphan market with a discrete prescriber base, it presents a tailor-made market opportunity for us, where peak annual net sales in the U.S. are expected to exceed $90 million, with total U.S. revenues during the 10-year forecast period projected to be greater than $700 million.

During this webcast, we also discussed at a high level the analysis that went into our determination to ultimately commercialize in the U.S. versus partnership. This decision was, in large part, based on maintaining 100% of HyBryte™'s value with a very reasonable

commercial build and launch expense of less than $10 million compared to us retaining less than half of its value with partnering. I would again urge all those that want to better understand what a unique value proposition HyBryte™ in CTCL represents to listen to the full webcast here.

We remain steadfast in our plans for partnership in the ex-U.S. markets and continue to pursue discussions with potential partners with similar reputation and expertise in this therapeutic area. We anticipate receiving marketing approval in the U.S. first, and with this approval in hand we will aggressively pursue marketing authorizations in other key markets worldwide. Given HyBryte™'s success in CTCL, we also are evaluating other potential cutaneous oncology indications that might similarly benefit from the use of our first-in-class synthetic hypericin.

The Company also has recently initiated a development program of the hypericin photodynamic therapy (PDT) in mild-to-moderate psoriasis, under the research name SGX302. Other PDTs have shown efficacy in psoriasis with a similar apoptotic mechanism, albeit using UV light associated with more severe potential long-term toxicities. With SGX302, the use of safe, visible light in the red-yellow spectrum has the advantage of penetrating deeper 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 employed DNA-damaging drugs and other phototherapies that are dependent on prolonged use of UV A or B exposure. The use of synthetic hypericin coupled with safe, visible light also avoids the risk of serious infections and cancer associated with the systemic immunosuppressive treatments used in psoriasis.

Psoriasis is an ongoing unmet medical need, with as many as 60-125 million people worldwide affected by this incurable disease. 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. Given the promising results with hypericin to date, including a small Phase 1/2 PoC clinical trial in mild-to-moderate psoriasis that demonstrated a robust 80% response, synthetic hypericin may have a role to play in helping patients suffering from this difficult to treat and chronic disease.

As stated by Neal Bhatia, MD, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego and an investigator in the Phase 3 FLASH study, "Similar to CTCL, psoriasis is a chronic disease where the management of side effects and toxicities is as important as the management of the disease itself. Having treated both CTCL and psoriasis

patients for over 20 years and having seen first-hand how they struggle to find good treatment options, access to an additional effective and safe therapy would add significantly to patient care and quality of life. The success of synthetic hypericin in targeting malignant T-cells during CTCL clinical trials is a promising indicator of the ability of SGX302 to provide a much-needed approach for the treatment of mild-to-moderate psoriasis, also caused by dysregulated T-cells. This success is further supported by both the previous synthetic hypericin PoC study in psoriasis and by the success, albeit confounded by potentially severe toxicity, of other photodynamic therapies in psoriasis."

As noted in our announcement, we plan to *initiate a follow-on Phase 2a clinical trial with SGX302 in mild-to-moderate psoriasis in the second half of 2022*. As we get closer to the study start, we will provide further details regarding trial design and timeline; however, a high level plan in the interim is to evaluate different topical formulations of synthetic hypericin to ensure optimal absorption for broadly treating this disease. In parallel, we will be working with our psoriasis clinical experts to finalize a protocol. Given our current cash position and the expected cost of the Phase 2a trial, we do not anticipate needing to raise additional capital to support this Phase 2a trial even as we continue to advance towards NDA filing and U.S. commercialization of HyBryte™ in the treatment of CTCL. Preliminary estimates of the potential worldwide psoriasis commercial market opportunity for SGX302 exceed $1 billion annually.

We previously announced top-line results for our pivotal Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) trial evaluating SGX942 (dusquetide) in the treatment of severe oral mucositis (SOM) in patients with HNC receiving chemoradiation. The study enrolled 268 patients randomized 1:1 to receive either SGX942 or placebo. The primary endpoint of median duration of SOM did not achieve statistical significance ($p \leq 0.05$); although biologic activity was clearly 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. Other secondary endpoints supported the biologic activity of dusquetide as well, including a statistically significant 50% reduction in the 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.

Despite the fact that SGX942 demonstrated clinically meaningful reductions in oral mucositis consistent with the previous Phase 2 study, we are disappointed the Phase 3 trial did not achieve the statistically significant benefit we expected. Over the last several months, we have been completing our analysis of the full dataset, including the 12-month long-term follow-up safety data. With this data in oral mucositis and given some of the difficulties experienced in the

recently completed Phase 3 study by Galera Therapeutics, we held a meeting with the MHRA to review the study results in order to obtain further clarity about 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.

Importantly, we also have further investigated the impact of SGX942 (dusquetide) on tumor burden in preclinical xenograft studies. These studies, similar to previous results, continued to demonstrate a potential direct anti-tumor effect of SGX942. This additional benefit of SGX942 is an important consideration in the oral mucositis treatment space. Other competitive considerations with SGX942 include its safety and ease of use. In particular, SGX942 is administered as a short 4-minute intravenous (IV) infusion twice weekly. For those following the oral mucositis development landscape, this contrasts significantly with Galera's recently completed Phase 3 oral mucositis study with Avasopasem. From what is available publicly, Avasopasem must be administered daily with radiation, within a short window of time of that daily radiation treatment and takes 60 minutes to administer IV. Interestingly, the recently reported incidence change observed in the Phase 3 Avasopasem trial (64% incidence in placebo, 54% treated) is favorably compared with the incidence change in the DOM-INNATE study (68% placebo, 58% SGX942). As well, the decrease in duration of SOM was similar between the two studies (18 days for Placebo vs. 8 days for Active in both studies). Given some of the recently announced complications with the Avasopasem results, and the significant inconveniences and logistical hurdles with its use, we continue to believe that SGX942 is the superior product. With the benefit of a robust preclinical and clinical data package for SGX942, we now will be analyzing the existing Phase 3 dataset from the DOM-INNATE study to design a second Phase 3 study and will look to identify a potential partner(s) to continue this development program.

In addition, we have been evaluating other disease indications with dusquetide and remain confident that there are a number of potential development paths forward with this unique compound. The unique mechanism of action of dusquetide, and the pathways in which its target protein, p62 or SQSTM-1, plays a pivotal role, support the potential role of dusquetide in oncology. Preclinical results have suggested a direct anti-tumor role for p62, which we have confirmed with more recent preclinical studies. Moreover, dusquetide continues to demonstrate an ability to act in concert with other tumor treatment regimens (i.e., chemotherapy, radiation therapy and targeted therapy).

Public Health Solutions Business Segment

This business segment is focused on the development of thermostable vaccines – a technology of increasingly appreciated importance as the requirements for worldwide distribution of vaccines to end the COVID-19 pandemic continues to be stifled by the logistical constraints of cold chain storage and shipping, as well as the massive scale of manufacturing required. This thermostabilization platform has demonstrated broad applicability in subunit protein vaccines, using both an antibody-focused adjuvant (alum), appropriate for anti-toxin vaccines for example, and a broader humoral and cell-mediated adjuvant (CoVaccine HT™), appropriate for anti-viral vaccines. The platform is currently being used to advance multiple vaccine candidates:

- RiVax®, an alum-adjuvanted ricin toxin vaccine based on a detoxified ricin toxin A-chain protein. The thermostabilized vaccine formulation has been shown to be both stable for extended periods at elevated temperatures (at least 12 months at 40 degrees Celsius or 104 degrees Fahrenheit) and highly durable (protecting mice for up to 12 months after vaccination). This program is advancing under the FDA "Animal Rule", with efficacy demonstrated not only in mice but in NHPs. RiVax®, as a new chemical entity, upon approval in the U.S., has the potential to qualify for a biodefense Priority Review Voucher (PRV). PRVs are transferable and can be sold, with sales in recent years of approximately $100 million. Additionally, RiVax® has received Orphan Drug designation and Fast Track designation from the FDA, as well as Orphan Drug designation from the EMA.

- Filovirus vaccine candidates, based on a similar thermostabilization process as RiVax® but utilizing the CoVaccine HT™ adjuvant combined with protein antigens based on the surface glycoproteins of *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus*. These highly lethal viruses have been associated with previous pandemics, and although logistically constrained vaccines (i.e., required freezing and/or refrigeration) have been approved for *Zaire ebolavirus*, there are no vaccines for the other filoviruses. This program, in collaboration with Dr. Axel Lehrer at the University of Hawaii at Manoa, has not only demonstrated efficacy in NHPs and the ability to thermostabilize the vaccines, but also has demonstrated the potential to create a single-vial presentation vaccine, stable at ambient temperatures, offering broad protection against multiple filoviruses by including more than one antigen. Effort now is focused on specific protection against *Sudan ebolavirus* and *Marburg marburgvirus* given the unmet medical need and U.S. government's funding prioritizations. Coupled with the logistical advantages of our single-vial presentation that does not require any refrigeration, we believe this thermostabilization vaccine platform is positioned for expansion in preparation for future pandemics. On the heels of the COVID-

19 pandemic, the U.S. government is accelerating its investment in pandemic preparedness, including having "the ability to rapidly make vaccines effective against any virus family". Specific initiatives have been spear-headed by the White House and Biden-Harris administration, as evidenced by the "American Pandemic Preparedness: Transforming Our Capabilities" white paper released in September 2021.

- CiVax™, a CoVaccine HT™ adjuvanted vaccine utilizing the pre-fusion stabilized form of the SARS-CoV-2 Spike protein. The combination of protein and adjuvant has been demonstrated to be broadly immunizing in both mice and NHPs, generating increased total antibodies, neutralizing antibodies and cell-mediated immune responses. Although the Spike protein utilized is from the Wuhan strain of the virus, neutralizing antibody responses have been demonstrated in vaccinated mice and NHPs against the Alpha, Beta, Gamma and Delta variants. Moreover, NHPs challenged with the Gamma variant up to 5 months after vaccination still demonstrated good protection, with lower peak viral titers and faster resolution of viral shedding. *We now are embarking on additional development looking at further protection from administering boosters and protection against exposure to the Omicron variant.*

We were awarded a Direct to Phase II Small Business Innovation Research grant of approximately $1.5 million from the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and Ebola Virus Disease vaccine candidates in conjunction with our CoVaccine HT™ (CoVaccine) adjuvant. This award also will support immune characterization of this novel, emulsified adjuvant that has unique potency and compatibility with lyophilization strategies to enable thermostabilization of subunit vaccines. We continue to advance these vaccine candidates while remaining active identifying and filing new grant and contract applications to secure additional sources of non-dilutive funding to support ongoing development.

Of additional note, in July 2020, we filed a demand for arbitration against Emergent BioSolutions, Inc. (EBS); Emergent Product Development Gaithersburg, Inc. (EPDG); and Emergent Manufacturing Operations Baltimore LLC (EMOB and together with EBS and EPDG, Emergent) with the American Arbitration Association in Mercer County, New Jersey which alleged that (a) EPDG breached a subcontract, a quality agreement, an express warranty, a warranty of merchantability, and a warranty of fitness for a particular purpose; (b) EMOB breached a quality agreement; (c) EPDG was unjustly enriched; (d) EPDG and EMOB were negligent in the performance of their work; and (e) EBS fraudulently induced us into entering into the contracts with EPDG and EMOB. Emergent has answered that demand for arbitration

denying the allegations and asserting affirmative defenses. We are seeking to recover damages of up to $19.0 million from Emergent. While we intend to vigorously pursue this arbitration, we cannot offer any assurances that we will recover any damages from Emergent. It is currently anticipated that an arbitration panel will render a decision in or before the July timeframe.

Balance Sheet and Capital

With approximately $29 million in cash reported in our Form 10-Q for the quarter ended September 30, 2021, not including our non-dilutive government funding, we now are sufficiently capitalized to achieve multiple key inflection points across our rare disease pipeline, including moving towards NDA and commercialization of HyBryte™. We also have other financial instruments at our disposal to judiciously supplement cash, if and when the need may arise:

- A $20 million strategic partnership with Pontifax Medison, the healthcare-dedicated venture and debt fund of the Pontifax life science funds. Under the terms of the partnership with Pontifax, we had access to up to $20 million in convertible debt financing in three tranches, which will mature over a four-and-a-half-year period and have an interest-only period for the first two years. Upon the closing of this transaction, we accessed the first tranche of $10 million. We elected to let the second tranche of $5 million expire in December 2021 and do not anticipate utilizing the third tranche of $5 available after the filing of the HyBryte™ NDA. Pontifax may elect to convert the outstanding loan drawn into shares of our common stock at any time prior to repayment at a conversion price of $4.10 per share. We also have the ability to force the conversion of the loan into shares of our common stock, subject to certain conditions.
- An at-the-market (ATM) sales issuance agreement with B. Riley Securities. Inc., available through a $30 million prospectus supplement put in place on our $50 million S-3 shelf registration this past August, with approximately $27 million remaining available on the ATM.

The combination of these two facilities provides significant cash runway into 2023. With a solid balance sheet and other available financing resources at our disposal, such as non-dilutive government funding, we are well positioned to aggressively advance and expand our pipeline. We also are continuing to pursue a number of strategic business opportunities, including but not limited to partnership and merger and acquisition, which may lead to more favorable capital inflows, including the potential to receive additional non-dilutive capital. Overall, we continue to remain mindful of dilution and will look at all future capital inflow initiatives in the most efficient and shareholder-friendly manner as possible.

In closing, thank you for your interest and your ongoing support of Soligenix. Although this past year has had its ups and downs, our future continues to hold significant promise, as does our late stage pipeline. We look forward to 2022, with the potential for multiple near-term catalysts on the horizon as we further advance our development programs towards commercialization. Best wishes!

Dr. Christopher J. Schaber
President and Chief Executive Officer
Soligenix, Inc.
January 10, 2022

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements, such as experienced with the COVID-19 outbreak. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the U.S. Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission, including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.