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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2022
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from to

Commission File Number: 001-36812

SALARIUS PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

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

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

Registrant's Telephone Number, Including Area Code**: (832) 834-6992**
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.
Yes ☐ No ☒

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes ☐ No ☒
As of June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock of the registrant held by non-affiliates of the registrant was $11,654,060 based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market on June 30, 2022.

As of March 20, 2023, there were 2,468,032 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:
Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SALARIUS PHARMACEUTICALS, INC.

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On October 14, 2022, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a 1-for-25 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split"), which became effective on October 14, 2022. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- *the Company's ability to continue as a going concern;*
- *the Company's planned strategy;*
- *the Company's clinical trials, including expected costs, goals, timing and other expectations related thereto;*
- *the potential advantages of its lead compound, seclidemstat or SP-2577, as a treatment for Ewing sarcoma, and other cancers and its ability to improve the life of patients;*
- *the potential for seclidemstat to target the epigenetic dysregulation underlying Ewing sarcoma;*
- *the future of the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR;*
- *the potential advantages of protein degraders including the value of SP-3164 as a cancer treatment;*
- *the expected impact that the addition of new clinical sites will have on the development of the Company's product candidates;*
- *the commercial or market opportunity and expansion for each therapeutic option, including the availability and value of a pediatric priority review voucher for in-clinic treatments and potential for accelerated approval;*
- *the Company's expectations as to revenue, cash flow, and expenses;*
- *the potential impact of the COVID-19 pandemic on the Company's business, operations, cash flow and ability to obtain additional financing;*
- *the Company's liquidity position, the expected sufficiency of such position for anticipated operating and capital requirements; and*
- *the ability of the Company to access additional financing under the Cancer Research Grant Contract with Cancer Prevention and Research Institute of Texas (CPRIT).*

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

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

- *Our ability to raise additional capital;*
- *our ability to resume enrollment in the Phase 1/2 trial of seclidemstat following its review of the available data surrounding the SUSAR;*
- *the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;*
- *the imposition of restrictions imposed by the FDA on the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR, including the partial clinical hold on November 1, 2022;*
- *the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials and regulatory submissions;*
- *fluctuations in our operating results;*

- *the success of current and future license and collaboration agreements;*
- *our dependence on contract research organizations, vendors and investigators;*
- *effects of competition and other developments affecting development of products;*
- *market acceptance of our product candidates;*
- *protection of intellectual property and avoiding intellectual property infringement;*
- *product liability; and*
- *other factors described in our filings with the SEC.*

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

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

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

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

Risks Related to our Ability to Continue as a Going Concern

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future which, together with our limited working capital and lack of revenue from product sales, raises substantial doubt about our financial viability and as to whether we will be able to continue as a going concern.

Risks Related to the Development of our Product Candidates

- Our ability to resume enrollment in the Phase 1/2 trial of seclidemstat following our review of the available data surrounding the SUSAR, including the partial clinical hold on November 1, 2022.
- Our approach to discovering and developing novel oncology therapeutics makes it difficult to predict timing and costs and obtaining regulatory approval may never lead to marketable products.
- Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities or our product candidates may cause undesirable side effects or have other properties that could limit the commercial viability or result in significant negative consequences.
- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical and clinical trials may not be predictive of future clinical trial results.
- We cannot give any assurance that our clinical trials will generate positive data for any of our product candidates or indications which we are pursuing.
- We may fail to capitalize on programs or product candidates that may be more profitable.
- We may find it difficult to enroll patients in our clinical trials.
- We may face potential product liability and incur substantial liability and costs and our regulatory approvals, if any, could be revoked or otherwise negatively impacted.

Risks Related to our Financial Condition and Capital Requirements

- We have never generated any revenue from product sales and may never generate revenue or be profitable.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

- Fast Track designation may not actually lead to a faster development or regulatory review or approval process. Additionally, FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for Fast Track.
- We may fail to obtain the necessary regulatory approvals to market our product candidates and may not be able to commercialize our product candidates.
- Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements, we may be subject to penalties if we fail to comply with regulatory requirements.
- Healthcare reform measures may have a material adverse effect on our business, financial condition or results of operations.
- We may be subject to fraud and abuse laws, false claims laws, and health information privacy and security laws under which we could become subject to substantial penalties.

- Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts and may impose requirements that limit our ability to take specified actions.

Risks Related to our Intellectual Property

- We may not be successful in obtaining or maintaining exclusive or other necessary rights to our targets, product compounds and processes for our development pipeline.
- We may not have sufficient patent term protections for our product candidates to protect our business.
- Changes in U.S. patent law could diminish the value of patents in general and could increase the uncertainties and costs surrounding prosecution and enforcement.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- The patent protection and patent prosecution for some of our product candidates is dependent on third parties.
- If we fail to comply with obligations in the agreements under which we licenses intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Risks Related to our Reliance on Third Parties

- If third parties on which we rely fail to obtain or maintain approval of government regulators, fail to comply with applicable regulations, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.
- We may be unable to realize the potential benefits of any current or future collaboration.

Risks Related to Commercialization of our Product Candidates

- We currently have very limited marketing and sales experience. Without the assistance of third parties, we may be unable to generate any revenue.
- We may be unable to form future collaborations with respect to our product candidates, which may cause us to alter our development and commercialization plans.
- If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our future revenue expectations and our business may suffer.
- Our competitors may discover, develop or commercialize products faster or more successfully than us.
- The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.
- We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates.

Risks Related to our Business Operations

- Our future success depends in part on our ability to retain key personnel and attract, retain, and motivate other qualified personnel.
- We will need to expand our organization and difficulties in managing growth could disrupt our operations.

Risks Related to Our Common Stock

- The terms of the warrants could impede our ability to enter into transactions or obtain additional financing.
- Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of our common stock.
- We do not currently intend to pay dividends on our common stock.

Part I

Item 1. Business

References to "Salarius," the "Company," "we," "us" and "our" refer to Salarius Pharmaceuticals, Inc. and its consolidated subsidiaries following the completion of the Merger and Salarius Pharmaceuticals, LLC prior to the completion of the Merger. References to "Notes" refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

Overview

Salarius Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, we are developing treatments for cancers caused by dysregulated gene expression, i.e., genes which are incorrectly turned on or off. We are developing two classes of drugs that address gene dysregulation: protein inhibitors and targeted protein degraders. Our technologies have the potential to work in both liquid and solid tumors. Our current pipeline consists of two primary compounds: 1) SP-3164, a small molecule protein degrader, and 2) seclidemstat (SP-2577), a small molecule inhibitor. Secondary compounds are in early stages of development.

Recent Events

Partial Clinical Hold

On October 18, 2022, the Company voluntarily paused new patient enrollment in its Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas per protocol design. The pause in new patient enrollment was due to a metastatic FET-rearranged sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). Upon review of the SUSAR and available information by the Company's independent Safety Review Committee for the clinical trial, patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. During a conference call with the U.S. Food and Drug Administration (FDA) on November 1, 2022, the FDA informed the Company that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, the FDA informed the Company that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA's clinical hold procedures provide the Company with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

Payments from Cancer Prevention and Research Institute of Texas

On February 15, 2023, the Company received $1.5 million from the Cancer Prevention and Research Institute of Texas. The payment is part of a non-dilutive grant of approximately $16.1 million awarded to support operations and development of the Company's drug candidate seclidemstat for the treatment of Ewing sarcoma. The $1.5 million payment brings the Company's cumulative disbursement from CPRIT to approximately $16.0 million. As of March 24, 2023, grant receivable from CPRIT is approximately $0.1million.

At the Market Offering

From January 27, 2023 through March 24, 2023, the Company sold 142,499 shares of its common shares with gross proceeds of approximately $0.4 million.

SP-3204 - Targeted Protein Degrader

On January 5, 2023 we announced the issuance of U.S. Patent No. 11,535,603, which covers our novel cereblon-binding protein degrader, SP-3204. SP-3204 is a GSPT1 protein degrader and has potential in hematological cancers.

Focused Programs

SP-3164 - A novel targeted protein degrader

The field of Targeted Protein Degradation (TPD) is rapidly growing and attracting a lot of interest from the biggest pharmaceutical companies. The two most common types of protein degraders are molecular glues (MGs) and proteolysis-targeting chimeras (PROTACs). SP-3164 is a next-generation cereblon-binding MG. The first generation MGs, lenalidomide (Revlimid®) and pomalidomide (Pomylast®), have had great success in treating hematological malignancies.

MGs are small molecules that commandeer the body's normal protein degradation processes by causing proteins to stick to one another thereby inducing selective degradation of cancer-causing proteins. Derived from avadomide, SP-3164 is engineered using DECS (deuterium-enabled chiral switching), a process that replaces hydrogen atoms with deuterium to stabilize the molecule's active enantiomer, resulting in a novel molecular entity with the potential for increased efficacy and improved safety compared to the 1st generation compound. SP-3164 degrades transcription factors IKZF1 (Ikaros) and IKZF3 (Aiolos), along with other proteins, resulting in both direct anti-cancer activity and immune-modulating properties. SP-3164 has potential in both hematologic and solid tumors and is currently in IND-enabling studies. In preclincial studies, SP-3164 demonstrated more efficient and robust degradation of Ikaros/Aiolos compared to lenalidomide and pomalidomide. Additionally, in animal models of lymphoma and multiple myeloma, treatment with SP-3164 resulted in significant tumor growth inhibition compared to control animals. When SP-3164 was combined with standard of care agents, the result was even more pronounced and in some cases resulted in complete regression of the tumors.

SP-2577

SP-2577 is a small-molecule LSD1 inhibitor with a novel scaffold. The molecule was discovered using structure-based computational screening coupled with chemical screening and further optimization with structure-activity relationship studies.

We believe that SP-2577 is different from the four other LSD1 inhibitors that have active clinical development programs because in addition to inhibiting LSD1's enzymatic activity, we also believe it more comprehensively inhibits LSD1's scaffolding properties. To our knowledge, SP-2577 is one of two reversible LSD1 inhibitors in clinical development. The three other LSD1 inhibitors in clinical development are irreversible inhibitors. SP-2577 has differentiated properties that may allow it to be developed in a broader range of cancer indications and in different combination regimens compared to the other LSD1 inhibitors in clinical development. Pharmacokinetic data indicates that SP-2577 can be given at dose levels that achieve drug exposure levels in patients above where activity was demonstrated in preclinical studies. We believe that SP-2577's profile will allow for more flexible dosing strategies by potentially having a wide therapeutic window. This is being studied and developed in our ongoing clinical program.

LSD1 Background

LSD1 is an enzyme that is, in part, responsible for epigenetic regulation of genes that support cancer growth. According to B. Majello, et al. in "Expanding the Role of the Histone Lysine-Specific Demethylase LSD1 in Cancer", LSD1 dysregulation is a key driver in multiple malignancies. LSD1 induces a cancer phenotype through its enzymatic activity and through its role as a scaffolding protein in epigenetic complexes. LSD1 is over-expressed in various cancers, and higher levels of LSD1 are often associated with poor prognosis in several types of cancer, making LSD1 inhibition an area of interest in cancer research.

Program Development

Our goal is to develop SP-3164 and SP-2577 for treatment of cancers while attempting to maximize return for investors. To achieve this goal, our strategy consists of a two-pronged approach: 1) speed-to-market by developing SP-3164 and SP-2577 in high unmet need indications and 2) expand the market by developing SP-3164 and SP-2577 in larger market indications.

SP-3164 Development

Our plan is to develop SP-3164 in high unmet need hematological indications and solid tumors. Our goal is to file an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for SP-3164 in the first half of 2023, and begin a Phase 1/2 clinical trial in the second half of 2023. SP-3164's development in hematological indications leverages clinical safety and efficacy data demonstrated by avadomide in hematological malignancies (e.g., Diffuse Large B cell Lymphoma, Follicular Lymphoma) across several clinical trials. SP-3164 is the stabilized, active S-enantiomer of avadomide, which exists as a 1:1 ratio of the S and R enantiomers. However, only the S-enantiomer is the active, anti-cancer species. Therefore, because SP-3164 is the stabilized S-

enantiomer, it has the potential to show improved therapy and safety over avadomide. SP-3164's potential has been demonstrated in in vitro studies and in preclinical mouse models of lymphoma and multiple myeloma. SP-3164 treatment showed robust anticancer activity in cells and tumored mouse models. Encouragingly, in lymphoma preclinical mouse models, treatment with SP-3164 combined with a standard of care agent resulted in complete tumor regressions.

Development of SP-2577 in Ewing Sarcoma Patients

Ewing sarcoma is a rare pediatric cancer with a lack of treatment options. FDA has put in place several different types of incentives for companies pursuing therapeutic treatments for such conditions. We have benefited from several of these incentives, including SP-2577's orphan designation and status designation as a potential treatment for a "rare pediatric disease." This means that if proven efficacious with a benefit-risk profile that the FDA judges to be positive and supportive of approval, SP-2577 could qualify for priority review and to receive a priority review voucher ("PRV"), although there can be no assurance that we will be able to do so. If received, we would have the ability to sell the PRV to other qualifying pharmaceutical companies. Additionally, in December 2019 we announced that SP-2577 had been granted Fast Track Designation by the FDA for the treatment of relapsed/refractory Ewing sarcoma patients. Fast Track is a process designed by the FDA to expedite the development and review of new drugs with the potential to treat serious or life-threatening conditions and fill unmet medical needs. The aim is to streamline the drug development and review process by allowing for more frequent communications with the agency to assure that questions and issues are resolved quickly, which often leads to earlier drug approval and access by patients. We initiated a Phase 1/2 clinical trial in the third quarter of 2018 and in the first quarter of 2021 we announced that the recommended Phase 2 dose (RP2D) had been established and the dose expansion phase of the trial would begin. We also announced that we will be combining SP-2577 with a commonly administered 2nd and 3rd line regimen, topotecan and cyclophosphamide in Ewing sarcoma. We hope that this modification will allow us to treat patients earlier in the continuum of care, increase the potential addressable patient population, and facilitate patient access to SP-2577. Additional clinical trials of SP-2577 will be necessary to receive FDA approval.

Disease background: Ewing sarcoma is a devastating pediatric and young adult cancer for which there are no approved targeted therapies. The cause of Ewing sarcoma is a chromosomal translocation involving the Ewing sarcoma breakpoint region 1 ("EWSR1") gene and ETS family genes, resulting in expression of a fusion oncoprotein. The resulting oncoprotein has been found to co-localize with LSD1 throughout the genome, making LSD1 an attractive therapeutic target for Ewing sarcoma. Based on data from the National Institute of Health ("NIH") and physician collaborators, we believe there are approximately 500 Ewing sarcoma patients diagnosed annually in the United States. Current treatment for Ewing sarcoma consists of an intensive chemotherapy regime, radiation and often disfiguring surgeries. Due to the harshness of current treatment options, children and adolescents often experience long-term side effects such as slowed growth and development, learning problems and an increased risk of developing second cancers. According to published literature, including "Management of recurrent Ewing sarcoma: challenges and approaches" by David Van Mater and Lars Wagner, patients with overt metastasis (20-30% of patients) or recurrent disease (~20%) have poor prognosis, with less than a 30% chance of experiencing disease-free survival, and there is currently not a standardized treatment available for recurrent Ewing sarcoma. These are the patients that we aim to help.

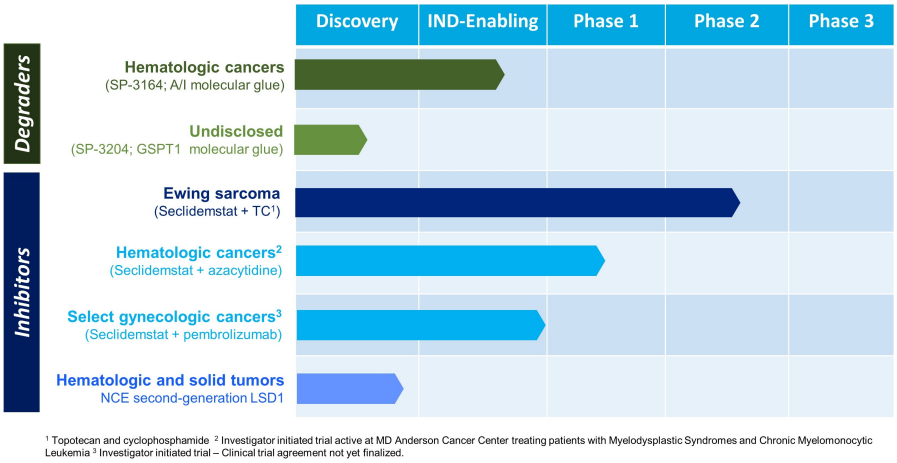
Expand SP-2577 Market by Pursuing Large Market Indications

As LSD1 can interact with over 60 regulatory proteins other than FET-fusion oncoproteins, we believe that LSD1 may also play a critical role in progression of various other cancer types.

In addition to solid tumors, SP-2577 has shown promising preclinical activity in hematologic cancers. In 2021 we announced the initiation of an MD Anderson Cancer Center sponsored Investigator Initiated Trial studying SP-2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). Myelodysplastic syndromes can progress into Acute Myeloid Leukemia (AML) and data from our ongoing trial could inform development of SP-2577 in hematologic cancers (also referred to as "liquid tumors" or "blood cancer"), including AML. The American Cancer Society estimates there were almost 20,000 new cases of AML in the US alone in 2020.

Recent data from "LSD1 Ablation Stimulates Anti-tumor Immunity and Enables Checkpoint Blockade" by W. Sheng, et al. and "Inhibition of Histone Lysine-specific Demethylase 1 Elicits Breast Tumor Immunity and Enhances Antitumor Efficacy of Immune Checkpoint Blockade" by Y. Qin, et al. suggests that LSD1 plays a role in tumor immune activity and can sensitize tumors to checkpoint inhibitors. These works have sparked interest in combining LSD1 inhibitors with checkpoint inhibitors.

The following figure lists our programs and their respective stages of development:



[1] Topotecan and cyclophosphamide [2] Investigator initiated trial active at MD Anderson Cancer Center treating patients with Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia [3] Investigator initiated trial – Clinical trial agreement not yet finalized.

Clinical Trials

Ewing Sarcoma

We are conducting a multi-site, open-label Phase 1/2 trial of SP-2577 for treatment of patients with relapsed/refractory Ewing sarcoma. Patients must have histologic confirmation of Ewing sarcoma that is refractory or recurrent and must have received one prior course of therapy for the disease. Among other inclusion criteria, patients must be 12 years or older and have a life expectancy of greater than 4 months.

The primary objectives of this clinical trial are to study the safety and tolerability of SP-2577. Secondary objectives include pharmacokinetic assessment, food effects on drug pharmacokinetics, determination of the maximum tolerated dose ("MTD") and assessment of preliminary signs of anti-tumor activity. Additionally, the trial will explore the use of circulating tumor cells ("CTCs"), cell-free DNA ("cfDNA"), Hemoglobin F and changes in molecular signatures of the tumor as pharmacodynamic markers of disease burden, drug effect and tumor response.

In February 2021, we announced that we reached the recommended phase 2 dose and would initiate the dose expansion portion of the trial. Ewing sarcoma patients will be treated in combination with topotecan/cyclophosphamide.

We have sixteen sites across the United States in our Phase 1/2 trial of SP-2577 for treatment of Ewing sarcoma.

In October 2022, the Company voluntarily paused new patient enrollment in its Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas per protocol design. The pause in new patient enrollment was due to a metastatic FET-rearranged sarcoma patient death, not an Ewing sarcoma patient death, that was classified as a suspected unexpected serious adverse reaction (SUSAR). Upon review of the SUSAR and available information by the Company's independent Safety Review Committee for the clinical trial, patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. During a conference call with the U.S. Food and Drug Administration (FDA) on November 1, 2022, the FDA informed the Company that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, FDA informed the Company that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA's clinical hold procedures provide the Company with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

Hematological Cancers

In June 2021 we announced the initiation of an Investigator Initiated Trial studying SP-2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). The Phase 1/2 trial is being led by Dr. Guillermo Montalban-Bravo from the Department of Leukemia at The University of Texas MD Anderson Cancer Center. The dose-escalation stage of the Phase 1/2 trial will enroll patients aged 18 and older with MDS or CMML. Patients will receive 75 mg/m2 of azacitidine, administered intravenously (IV) or subcutaneously (SC), on days one through seven of each 28-day cycle in combination with an escalating, twice-daily dose of seclidemstat administered as an oral tablet. Once the MTD of the combination is determined by the Safety Review Committee, the dose-expansion stage is planned that will include additional patients to confirm the safety and tolerability profile for seclidemstat in combination with azacitidine and capture efficacy data regarding overall response rate, duration of response, leukemia-free survival, relapse-free survival, and overall survival.

In October, 2022, in response to the Company voluntarily pausing the Phase 1/2 trial of seclidemstat as a treatment in Ewing sarcoma and FET-rearranged sarcomas, MD Anderson also voluntarily paused new patient enrollment. The FDA informed MD Anderson that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided notification that the MDS and CMML trial was on partial clinical hold. While on partial clinical hold, FDA informed MD Anderson that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA's clinical hold procedures provide the Company with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

Strategic Agreements

Listed below are the strategic agreements that may have an impact on our results of operations:

The University of Utah Research Foundation

On August 3, 2011, we entered into an Exclusive License Agreement with the University of Utah Research Foundation (the "University of Utah"), for the exclusive license with respect to patent rights protecting SP-2577 and related compounds. The patent rights were for a provisional patent. The term of agreement is until the last-to-expire of the patent rights licensed under the agreement, which is expected to be as late as 2037, unless otherwise terminated by law or by the parties pursuant to the agreement.

In further consideration of the rights granted by the University of Utah, we agreed to pay all past patent expenses incurred in filing and prosecuting the patent application, and pay all future patent expenses incurred including filing, prosecuting, enforcing and maintaining the patent right.

Under the terms of the agreement, we may be obligated to make certain future milestone and royalty payments, including: (i) an earned royalty payment based on a single digit percentage of net sales and a required minimum annual royalty payment commencing with the third full calendar year after the first commercial sale in the U.S., Germany, France, Japan or the U.K. ranging from $10,000 to $40,000 per year which minimum payments are fully creditable towards the earned royalty payment with respect to the relevant calendar year, (ii) a sublicensee fee based on a single digit percentage of revenues received by sublicensees, (iii) milestone payments in agreed dollar amounts upon receiving regulatory approvals allowing the marketing and sale of licensed products or licensed methods relating to the patients' rights in each of the U.S., the European Union and Japan not exceeding $150,000 in the aggregate and (iv) a milestone payment in an agreed dollar amount upon the two year anniversary of the first commercial sale of a licensed product not exceeding $1.0 million.

Either party has a right to terminate the agreement for a breach of or default under the agreement following a 60-day cure period. If we ceases to carry on our business with respect to the patent right granted under the agreement, the University of Utah has a right to terminate the agreement upon 60 days' notice. In addition, we may terminate the agreement at any time upon ninety days' notice to the University of Utah.

Cancer Prevention and Research Institute of Texas

In June 2016, we entered into a Cancer Research Grant Contract with Cancer Prevention and Research Institute of Texas ("CPRIT"). The grant contract was for an amount up to $18.7 million to fund the development of LSD-1 inhibitor. The grant was subsequently amended to remove $2.6 million related to a discontinued prostate cancer

program. This is a 3-year grant award which originally expired on May 31, 2019. The grant now expires on May 31, 2023. The Company has applied for extension until November 30, 2023. As of March 24, 2023 grant receivable balance from CPRIT is approximately $0.1 million.

Upon commercialization of SP-2577, and if our revenue is above a specified dollar threshold, we will be required to pay up to 3%-5% of such revenue during the revenue term until CPRIT receives an amount equal to a single digit multiple of the total grant award. The revenue term is determined on a country by country basis as revenue during the period beginning on the date of the first commercial sale of a product or service until there no longer exists any exclusivity for a commercial product or service in such country, which may be as late as 2037. In the event CPRIT receives such specified percentage of the total grant award from us during the revenue term, we will continue to pay CPRIT a reduced revenue sharing percentage during the remainder of the revenue term. Additionally, if we are required to obtain a license under the intellectual property rights of one or more third parties in order to sell commercial products in any given country, then the revenue sharing percentages may be reduced.

The agreement may be terminated by the mutual consent of the parties or by us at our discretion. CPRIT may also terminate the agreement upon an event of default, which includes our failure to conduct the project within the scope agreed by the parties, our material breach of the agreement, our failure to comply with applicable law, or bankruptcy or discontinuation of our business operations, among others. In addition, the agreement may be terminated by CPRIT if the allocated funds become legally unavailable during the term and CPRIT is unable to obtain additional funds for such purposes. If CPRIT terminates the agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us to repay some or all of the disbursed grant.

DeuteRx, LLC

On January 12, 2022, we entered into the ASCA with DeuteRx, LLC, pursuant to which we acquired targeted protein development portfolio.

The portfolio was purchased for an aggregate purchase price of $1,500,000 and the delivery of 40,000 shares of our common stock. We also agreed to pay to Seller (i) milestone payments upon the occurrence of certain events and (ii) royalty payments. All cost related to the transaction were immediately expensed in 2022 as acquired in-process research and development expenses since SP-3164 has not yet achieved regulatory approval and, absent obtaining such approval, has no alternative future use. A member of the Company's Board of Directors also serves as a consultant to the Seller and is employed by an affiliate of the Seller.

Simultaneously with our entry into the ASCA, we and DeuteRx entered into the R&D Services Agreement, which sets forth the terms and conditions upon which DeuteRx will provide services to us, including the implementation and performance of a Non-Clinical and Clinical Development Scope of Work.

Manufacturing, Sales and Marketing

The Company currently has no manufacturing facilities, nor does it have a sales and marketing organization because our product candidates are still in preclinical or early-stage clinical development.

Intellectual Property

As of December 31, 2022, we had a SP-2577 worldwide portfolio of 71 patents and patent applications of which 64 were issued or allowed and 7 are pending applications. This portfolio includes (i) composition of matter and methods of use patents on our lead candidate, SP-2577. Transaction have claims that cover the composition of matter of SP-3164 with a patent term expiration of January 14, 2034. The patents and patent applications related to SP-2577 are owned by the University of Utah Research Foundation and are exclusively licensed to us.

In the United States, our anticipated first target market, we have two composition of matter patents (US#8,987,335 and US#9,266,838) and two methods of use patents (US#9,642,857, US#9,555,024) protecting SP-2577 and related compounds which will expire in 2032.

As of December 31, 2022 the targeted degradation patent portfolio consisted of 5 patent families with 13 granted patents and 4 pending applications acquired in the DeuteRx Transaction.

In addition to patent protection, we seek to rely on trade secret protection, trademark protection and know-how to expand our proprietary position around our chemistry, technology and other discoveries and inventions that we consider important to our business. We also seek to protect our intellectual property in part by entering into confidentiality agreements with our employees, consultants, scientific advisors, clinical investigators and other contractors and by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them. Further, we seek trademark protection in the United States and internationally where available and when we deem appropriate.

Competition

SP-3164: Targeted Protein Degradation and Competitive Differentiation

The field of Targeted Protein Degradation (TPD) is rapidly growing and attracting a lot of interest from the biggest pharmaceutical companies. The two most common types of protein degraders are molecular glues (MGs) and proteolysis-targeting chimeras (PROTACs). SP-3164 is a next-generation CRBN-binding MG. There are several MGs in clinical development (see table below for select MGs in development) and additional compounds in IND-enabling studies.

Compound Name	Company	Main Protein Targets	Indications (Phase of development)
Iberdomide (CC-220)	Bristol Myers Squibb (BMS)	Ikaros/Aiolos (I/A)	MM (Phase 3), NHL (Phase 1/2)
Mezigdomide (CC-92480)	BMS	I/A	R/R MM and ND MM (Phase 3)
CC-99282	BMS	I/A	NHL (Phase 1b), CLL (Phase 1b)
CFT7455	C4 Therapeutics	I/A	NHL and MM (Phase 1)
BTX-1188	BioTheryX	GSPT1, I/A	AST, NHL and AML (Phase 1)

To the best of our knowledge, SP-3164 will be the first, deuterium- stabilized cereblon-binding drug to enter the clinic. Based on preclinical studies, SP-3164 may have advantageous pharmacokinetic properties that could increase tolerability. Compared to MGs currently on the market including Revlimid® and Pomalyst®, SP-3164 showed more robust degradation of Ikaros and Aiolos and resulted in improved tumor growth inhibition in mouse models. In addition, although SP-3164 is currently in IND-enabling studies, there is extensive clinical data generated by the first-generation compound, avadomide, that SP-3164 can build upon. This includes development of a precision medicine approach to select for patients who may be more sensitive to SP-3164.

SP-2577: LSD1 Inhibition and Competitive Differentiation

LSD1 is a widely published epigenetic target and has attracted interest from several large pharmaceutical companies. LSD1 helps drive cancer progression through demethylation of histones and by acting as a scaffolding protein within various activator and repressor complexes. According to clinicaltrials.gov, there are four targeted LSD1 inhibitors and one dual LSD1/HDAC6 inhibitor (JBI-295) in Phase 1/2 clinical development for a variety of cancer types (shown in the table below).

Company	Binding Mechanism	Drug Name	Latest Phase
Salarius	Reversible	SP-2577	Phase 1/2
Oryzon	Irreversible	ORY-1001	Phase 2
Celgene/Bristol Myers Squibb	Reversible	CC-90011	Phase 2
Imago	Irreversible	IMG-7289	Phase 2
Jubilant	Irreversible	JBI-295	Phase 1

We believe that SP-2577 is differentiated in its ability to effectively inhibit LSD1's scaffolding properties in addition to LSD1's demethylation activity. Compared to irreversible LSD1 inhibitors, our molecule has a novel binding mechanism (reversible as opposed to irreversible) and binding location (closer to substrate binding site as opposed to the FAD cofactor of LSD1). This was demonstrated in a study conducted by A. Sehrawat, et al. in "LSD1 activates

a Lethal Prostate Cancer Gene Network Independently of its Demethylase Function" with SP-2509, an analogue of SP-2577. Compared to LSD1 inhibitors in clinical development, SP-2577 binds to LSD1 in a different manner, which we hypothesizes may grant it therapeutic advantages over the competition. To further justify this hypothesis, we compared the affect of SP-2577, GSK-LSD1 (analogue to GSK's former clinical candidate), CC-90011 (Celgene's reversible, enzymatic inhibiting clinical candidate), and ORY-1001 (Oryzon's irreversible, enzymatic-inhibiting clinical candidate) on cell viability in vitro. SP-2577 was able to better inhibit cell growth across 32 cancer cell types compared to GSK-LSD1, 20 cell types compared to CC-90011, and 40 cell lines compared to ORY-1001.

Government Regulation and Product Approvals

United States Government Regulation

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

Drug Development Process

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

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

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

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

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

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

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

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

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in vitro testing and other sources that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the

sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

In limited circumstances, the FDA also permits the administration of investigational drug products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the biological product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Process

After completion of the required clinical testing, a sponsor may prepare and submit an NDA to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all non-clinical, clinical and other testing and a compilation of data relating to the product's toxicology, pharmacology, chemistry, manufacture and controls. In addition, under the Pediatric Research Equity Act, as amended, an NDA or supplement to an NDA generally must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Under the Prescription Drug User Fee Act ("PDUFA") performance goals that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA, because the FDA has approximately two months to make a "filing" decision. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to 6 months of the "filing" date for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

Within 60 days following submission of the application, the FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may issue a refuse-to-file letter and request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility(ies) in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee-typically a panel that includes clinicians and other experts-for consideration, discussion and a vote on specific questions relevant to the approval decision. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

During the NDA review process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required. A REMS could

include a medication guide, communication plan or elements to assure safe use, such as required healthcare provider or pharmacy certification, a patient registry and other safe use conditions.

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

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

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

Orphan Drug Status

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

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

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

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

Expedited Development and Review Programs

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

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug product designated for priority review in an effort to facilitate the review on a 6 month, rather than the standard 10 month, timeline. We have received FDA designation as a potential treatment for a rare pediatric disease for the use of SP-2577 in Ewing's Sarcoma. Should SP-2577 prove to be efficacious in this disease with a positive benefit/risk ratio, we expect to receive a Priority Review Voucher. The Priority Review Voucher is transferable and may be sold.

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

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

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

Post-Approval Requirements

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

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Foreign Regulation

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

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

Other Healthcare Laws

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

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration in cash or in kind that is intended to induce or reward the referral of business, including the purchase, order, or lease of any, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers and beneficiaries on the other.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have found that the Anti-Kickback Statute may be violated if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program business. In addition, liability may be established without actual knowledge of the statute or specific intent to violate it. Violations of this law are punishable by up to ten years in prison, and can also result in criminal fines, civil money penalties and exclusion from participation in federal healthcare programs.

Moreover, 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 federal civil False Claims Act.

The federal civil False Claims Act, prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $13,508 and $27,018 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

The healthcare fraud provisions of the Health Insurance Portability and Accountability Act (“HIPAA”) prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have analogous laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require pharmaceutical companies to

comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to certain healthcare providers; laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state laws and local ordinances that require identification or licensing of sales representatives.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as certain persons or entities that create, receive, maintain or transmit protected health information in connection with providing a specified service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. Although we are not directly subject to HIPAA, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA, and other privacy and data security and consumer protection laws, and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, and subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The U.S. federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members.

Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal control to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, the Patient Protection and Affordable Care Act, as amended, (the "ACA") has had, and is expected to continue to have, a significant impact on the healthcare industry. The ACA was designed to expand coverage for the

uninsured while at the same time containing overall healthcare costs, among other objectives. With regard to pharmaceutical products, among other things, the ACA revised the definition of "average manufacturer price" for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and imposed a significant annual fee on companies that manufacture or import certain branded prescription drug products. It is unclear how efforts to modify or challenge the ACA or its implementing regulations, or portions thereof, will affect our business. Additional legislative and regulatory changes, and further judicial challenges, related to the ACA remain possible. Any such changes or challenges could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These included reductions to Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031.

Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to types of several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, the Drug Supply Chain Security Act, enacted in 2013, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which will be phased in over several years beginning in 2016. Among the requirements of this legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law. The IRA introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates.

It is possible that the ACA, as currently enacted or as may be amended in the future, as well as other healthcare reform measures, may result in more rigorous coverage criteria and less favorable payment methodologies, or other downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction or restriction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or successfully commercialize our products.

Coverage and Reimbursement

Sales of our product candidates, once approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our product candidates, and any future product candidates, will therefore depend substantially on the extent to which the costs of our product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for our product candidates, and any future product candidates, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls and transparency requirements, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations and financial condition. In addition, state and federal healthcare reform measures have been and 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 products once approved or additional pricing pressures.

Facilities

Our principal executive offices are in the Texas Medical Center in Houston, Texas, under a month-to-month lease. This facility consists of approximately 1,000 square feet and accommodates our general and administrative activities. Additionally, we lease laboratory space from Johnson & Johnson, JLABS facility located adjacent to our corporate office. We do not own any real property. We believe that our leased facility is adequate to meet our current needs and that additional facilities will be available on commercially reasonable terms to meet our future needs.

Employees and Human Capital Resources

As of March 8, 2023, we had 12 full-time employees. We have never had a work stoppage, and none of our employees are represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal Proceedings

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

Corporate Information and Web Site Access to SEC Filings

The Company was initially incorporated as Flex Pharma, Inc. in Delaware in February 2014. In July 2019, we changed our named to Salarius Pharmaceuticals, Inc. Our principal executive offices are located at 2450 Holcombe Blvd., Suite X, Houston, TX 77021, and our telephone number is (832) 834-6992. Our website address is www.salariuspharma.com. The public can obtain any documents that we file with the SEC at http://www.sec.gov.

Item 1A. Risk Factors

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

Risks Related to our Ability to Continue as a Going Concern

We have incurred losses since our inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future which together with our limited working capital, and lack of revenue from product sales, raises substantial doubt about our financial viability and as to whether we will be able to continue as a going concern.

Our auditor's report on our financial statements for the year ended December 31, 2022, includes an explanatory paragraph related to the existence of substantial doubt about our ability to continue as a going concern. We are a clinical development-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have primarily financed our operations through equity financings and a grant from CPRIT. We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $31.6 million and $12.8 million for each of the years ended December 31, 2022 and December 31, 2021.

We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. We cannot be certain that additional funding will be available on acceptable terms, or at all, for a number of reasons, including market conditions, and the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to continue operations. Further, if we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to (i) delay, limit, reduce or terminate the drug development of our current or future product candidates, or seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or (ii) significantly curtail our operations, liquidate our assets or seek bankruptcy. The aforementioned factors, which are largely outside of our control, raise substantial doubt about our ability to continue as a going concern within one year from the date of filing of this annual report. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

We have devoted substantially all our financial resources to identify, acquire, and develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and ability to obtain funding through equity or debt financings,

strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative and competitive undertaking and involves a substantial degree of risk. We expect losses to increase as we complete Phase 1 development and advance into Phase 2 development of our lead product candidates. It may be several years, if ever, before we complete pivotal clinical trials and have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to regulatory approval. We expect to be required to expend a significant amount of funds before we know if we have a clinically successful product candidate.

Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates;
- continue efforts to discover new product candidates;
- undertake the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our programs into larger, more expensive clinical trials;
- initiate additional pre-clinical, clinical, or other trials or studies for our product candidates;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounters issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Risks Related to the Development of our Product Candidates

It may take considerable time and expense to resolve the partial clinical hold that has been placed on our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas by the FDA, and no assurance can be given that the FDA will remove the partial clinical hold, in which case our business and prospects will likely suffer material adverse consequences.

On October 18, 2022, we announced that per protocol design, we voluntarily paused new patient enrollment in our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas. The pause in new patient enrollment was due to a metastatic FET-rearranged sarcoma patient death, not an Ewing sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). At the time, we also announced that our independent Safety Review Committee for the clinical trial determined that patients currently receiving seclidemstat treatment could continue treatment after consulting with their physician.

During a conference call with the US Food and Drug Administration (FDA) on Tuesday, November 1, 2022, the FDA informed us that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, FDA informed us that the pause in patient enrollment shall remain in place and

patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA's clinical hold procedures provide us with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

It may take a considerable period of time, the length of which is not certain at this time, and expense for us to fully analyze the available data and address the FDA's concerns. Even if we are able to fully respond to the FDA's concerns, the FDA may subsequently make additional requests that we would need to fulfill prior to the lifting of the partial clinical hold. It is possible that we will be unable to fully address the FDA's concerns and as a result the partial clinical hold may never be lifted and we may never be able to enroll new patients in the clinical trial, , which could have a material adverse effect on our business and prospects.

The approach we are taking to discover and develop novel oncology therapeutics using epigenetic enzymes to moderate transcription factors and thereby control abnormal protein expression is unproven and may never lead to marketable products.

The scientific discoveries that form the basis for our efforts to discover and develop our current product candidates are relatively recent. To date, neither we nor any other company has received regulatory approval to market therapeutics using epigenetic enzymes. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. The Successful development of therapeutic products will require solving a number of issues. In addition, any product candidates that we develop may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory and pre-clinical trials, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. For instance, our clinical and pre-clinical data to date is not validated and we have no way of knowing if after validation our clinical trial data will be complete and consistent. If we do not successfully develop and commercialize product candidates based upon this technological approach, we may not become profitable and the value of our capital stock may decline.

Further, our focus on epigenetic enzyme technology for developing product candidates as opposed to multiple, more proven technologies for drug development increases the risk associated with our business. If we are not successful in developing an approved product using our technology, we may not be able to identify and successfully implement an alternative product development strategy. In addition, work by other companies pursuing similar technologies may encounter setbacks and difficulties that regulators and investors may attribute to our product candidates, whether appropriate or not.

Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more of our clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- the inability to generate satisfactory pre-clinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of our clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations, ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays and inability in recruiting qualified patients in our clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;

- failure by clinical sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by our clinical sites, CROs or other third parties to perform in accordance with contractual obligations or the regulatory requirements of the FDA, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical trials;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- adverse events or tolerability or animal toxicology issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of the clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;
- evolution in the standard of care that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for our product candidates could result in additional costs or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional pre-clinical trials or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

Our therapeutic product candidates are based on a relatively novel technology, which makes it difficult to predict the timing and cost of development and of subsequently obtaining regulatory approval, if at all.

We have concentrated our research and development efforts to date on a limited number of product candidates based on our epigenetic enzyme therapeutic platform and identifying our initial targeted disease indications. Our future success depends on our successful development of viable product candidates. Currently, only one of our product candidates (seclidemstat) is in Phase 1 clinical development, and the remainder of our product candidates are in pre-clinical development. There can be no assurance that we will not experience problems or delays in developing our product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved.

The clinical trial and manufacturing requirements of the FDA, the European Medicines Agency and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as epigenetic enzyme therapeutics can be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates, even if approved for marketing. Approvals by the European Commission may not be indicative of what the FDA, and vice versa, may require for approval and different or additional pre-clinical trials or clinical trials may be required to support regulatory approval in each respective jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us, an IRB or ethics committee, or regulatory authorities to interrupt, delay, or terminate clinical trials or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities and potential product liability claims.

In addition, to date our product candidates have been studied in only a very limited number of patients. Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. We may experience a high rates or severity of adverse events and comparable or high rates of discontinuation in testing in our future clinical trials. There is no guarantee that severe side effects will not be identified through ongoing clinical trials of our product candidates for current and other indications. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for their proposed indications. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization. Specifically, as a result of concerns regarding the potential teratogenic and abortifacient effects of SP-2577, pregnant women were excluded from the conducted studies.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including but not limited to:

- our clinical trials may be put on hold, such as the partial clinical hold that has been placed on our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- We may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- We could be sued and held liable for harm caused to patients; and
- its reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm or cause the complete failure of our business, results of operations, and prospects.

Some of our product candidates may produce results in pre-clinical or clinical settings for indications other than those for which we contemplate conducting development activities or seeking FDA approval, and we cannot give any assurance that our clinical trials will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized.

We currently have one product candidate, seclidemstat, in Phase 1/2 clinical trials for Ewing sarcoma and FET-rearranged sarcomas. There can be no assurance that the data that we develop for our product candidates in our planned indications will be sufficient to obtain regulatory approval.

In addition, none of our product candidates have advanced into a pivotal clinical trial for our proposed indications and it may be years before any such clinical trial is initiated and completed, if at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical and clinical trials may not be predictive of future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical trials and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in limited numbers of clinical sites for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses. We cannot assure whether any Phase 1, Phase 2, Phase 3, or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market our drug candidates.

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

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with some programs or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied. Difficulty in enrolling patients is a common hurdle faced by early stage biotechnology companies and could, and often does, delay or prevent clinical trials of product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment.

Patient enrollment is affected by several factors, including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of patients to participate in our clinical trials;
- proximity and availability of clinical trial sites for prospective patients;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies.

The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials,

and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs which could be greater than our insurance coverage or overall resources. If the use or misuse of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Patients with the diseases targeted by our product candidates may already be in severe and advanced stages of disease and have both known and unknown significant preexisting and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Although we have product liability insurance, which covers our clinical trials in the United States, for up to $2.0 million per occurrence, up to an aggregate limit of $5.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will also likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plans to initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we requires it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenues;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourself;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to our Financial Condition and Capital Requirements

We have never generated any revenue from product sales and may never generate revenue or be profitable.

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining reimbursement or pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Portions of our current pipeline of product candidates have been in-licensed from third parties, which make the commercial sale of such in-licensed products potentially subject to additional royalty and milestone payments to such third parties. We will also

have to develop, contract for or acquire manufacturing capabilities to continue development and potential commercialization of our product candidates. We will need to develop or procure our drug product in a commercially feasible manner in order to successfully commercialize any future approved product; if any. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

We received substantial funding during the year ended December 31, 2022 including reimbursement from CPRIT. Other than the CPRIT funding, these raises caused significant dilution to stockholders who owned our shares of Common Stock prior to these capital raises. To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our equity holders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

We have also historically received funds from state and federal government grants for research and development including CPRIT. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth below under the risk factor titled “Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take specified actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.” Although we might apply for government contracts and grants in the future, we cannot assure you that we will be successful in obtaining additional grants for any product candidates or programs. Failure to receive additional government grants in the future may substantially harm our business.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

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

We may seek a breakthrough therapy designation from the FDA for some of our product candidates that reach the regulatory review process. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

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

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

We have received Fast Track designation for one of our product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process. Additionally, FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for Fast Track.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. We recently received Fast Track designation for a product candidate. However, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, regulatory authorities.

The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price.

To obtain marketing approval, United States laws require:

- controlled research and human clinical testing;
- establishment of the safety and efficacy of the product for each use sought;
- government review and approval of a submission containing, among other things, manufacturing, pre-clinical and clinical data; and
- compliance with cGMP regulations.

The process of reviewing and approving a drug is time-consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a

significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that our candidate is safe and effective for the proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that the product candidate's benefits outweigh its risks;
- disagreement with our interpretation of pre-clinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.
- The FDA or a comparable regulatory authority outside the United States may require us to conduct additional pre-clinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely affected.

Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements, which may result in significant additional expense and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, marketing, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue fines, untitled letters or warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;

- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- product seizure or detention or refusal to permit the import or export of products;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- impose restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and our operating results would be adversely affected.

Healthcare reform measures may have a material adverse effect on our business, financial condition or results of operations.

In the United States, there have been and continue to be a number of initiatives to contain healthcare costs or otherwise change or reform the provision of healthcare products and services to the patient population. For example, in March 2010, the ACA was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of specified branded prescription drugs, and established a new Medicare Part D coverage gap discount program. Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to modify them or alter their interpretation or implementation. It is unclear how efforts to challenge or modify the ACA or its implementing regulations, or portions thereof, will affect our business.

The IRA, which was enacted into law on August 16, 2022, introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted and we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product candidates, if commercialized, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or successfully commercialize our product candidates.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and federal and state transparency laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. These laws, which are described in further detail in Government Regulation and Product Approvals – Other Healthcare Laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the U.S. federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, laws that require manufacturers to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same scope or application, thus complicating compliance efforts.

Efforts to ensure that our collaborations with third parties, and our business generally, will comply with applicable United States and 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 laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, contractual damages, reputational harm, disgorgement, curtailment or restricting of our operations, any of which could substantially disrupt our operations and diminish our profits and future earnings. 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. The risk of our being

found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take specified actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.

During the course of our development of our product candidates, we have been funded in part through federal and state grants, including but not limited to the funding we received from CPRIT. If CPRIT terminates the agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us to repay some or all of the disbursed grant.

In addition to the funding we have received to date, we intend to continue to apply for federal and state grants to receive additional funding in the future. Contracts and grants funded by the U.S. government, state governments and their related agencies include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- require repayment of all or a portion of the grant proceeds, in specified cases with interest, in the event we violate specified covenants pertaining to various matters that include a failure to achieve specified milestones or to comply with terms relating to use of grant proceeds, or failure to comply with specified laws;
- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- impose qualifications for the engagement of manufacturers, suppliers and other contractors as well as other criteria for reimbursements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

In addition to those powers set forth above, the government funding we may receive could also impose requirements to make payments based upon sales of our products, if any, in the future.

We may not have the right to prohibit the U.S. government from using specified technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts. These and other provisions of government grants may also apply to intellectual property we license now or in the future.

In addition, government contracts and grants normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of some contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs and liabilities that could have a material adverse effect on our business, financial condition or results of operations.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to our targets, product compounds and processes for our development pipeline through acquisitions and in-licenses.

Presently, we have rights to the intellectual property, through licenses from third parties and under patents and patent applications that we own, to modulate only a subset of the known epigenetic enzyme targets. Because our programs may involve a range of targets, including targets that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have previously and may continue to collaborate with academic institutions worldwide to accelerate our pre-clinical and clinical research or development under written agreements with these institutions. Typically, these institutions provide an option to negotiate a license to any of the institution's rights in technology

resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-licenses may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on specified delays caused by the applicant(s) or the U.S. Patent and Trademark Office ("USPTO").

Depending on the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for patent term extension under the Hatch-Waxman Act. Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product may not extend beyond the current patent expiration dates and competitors may obtain approval to market competing products sooner. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other biotechnology companies, our success is heavily dependent on patents and the ability to enforce and protect these patients. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Some of our patent claims may be affected by the recent U.S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics. In Myriad, the Supreme Court held that unmodified isolated fragments of genomic sequences, such as the DNA constituting the BRCA1 and BRCA2 genes, are not eligible for patent protection because they constitute a product of nature. The exact boundaries of the Supreme Court's decision remain unclear as the Supreme Court did not address other types of nucleic acids.

On December 16, 2014, the USPTO issued guidance to patent examiners titled 2014 Interim Guidance on Patent Subject Matter Eligibility (Fed. Reg. 79 (241): 74618-33. These guidelines instruct USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids. In addition, the USPTO continues to provide updates to its guidance and this is a developing area. The recent USPTO guidance could make it impossible for us to pursue similar patent claims in patent applications we may prosecute in the future.

Our patent portfolio contains claims of various types and scope, including chemically modified mimics, as well as methods of medical treatment. The presence of varying claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges under Myriad or future judicial decisions. However, it is not yet clear what, if any, impact this recent Supreme Court decision or future decisions will have on the operation of our business.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not come into effect until March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act

and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition or results of operations.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under such change, a third party that files a patent application in the USPTO after that date, but before we could, may be awarded a patent covering an invention of our even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as Inter Partes Review ("IPR"), which has been generally used by many third parties over the past two years to invalidate patents. The IPR process is not limited to patents filed after the Leahy-Smith Act was enacted, and would therefore be available to a third party seeking to invalidate any of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our proposed markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seeks to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties.

Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of epigenetic enzyme inhibitors and related technologies. We are aware of U.S. and foreign patents and pending patent applications owned by third parties that cover therapeutic uses of epigenetic inhibitors. We are currently monitoring these patents and patent applications. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates, as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against we may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in meeting our obligations under our existing license agreements necessary to maintain our product candidate licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to license

or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

We collaborate with academic institutions worldwide to identify product candidates, accelerate our research and conduct development. Typically, these institutions have provided us with an option to negotiate an exclusive license to any of the institution's rights in the patents or other intellectual property resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program that we wish to pursue.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third-party, and our business and financial condition could suffer.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gains the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. If future licensors fail to appropriately and broadly prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to assuming control over patent prosecution.

If we fail to comply with obligations in the agreements under which we licenses intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to intellectual property licenses and supply agreements that are important to our business and may enter into additional license agreements in the future. Our existing agreements impose, and we expect that future license agreements will impose on us, various diligence, milestone payment, royalty, purchasing, and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture, or market products covered by the license or subject to supply commitments.

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

Competitors may infringe our patents or the patents of our licensors. If we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, clarity or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and makes every effort to ensure that our employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to our Reliance on Third Parties

We rely on or will rely on third parties to conduct our clinical trials, manufacture our product candidates and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plans to continue to rely upon third-parties such as CROs, hospitals, etc. to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and manages and controls only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require

us to perform additional clinical trials before approving our marketing applications. We cannot be assured that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process.

If any of our relationships with these third-parties terminate, we may not be able to enter into arrangements with alternative third parties in a timely manner or do so on commercially reasonable terms. In addition, third parties may not prioritize our clinical trials relative to those of other customers and any turnover in personnel or delays in the allocation of third party employees may negatively affect our clinical trials. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CROs, in particular, may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

In addition, we do not currently have, nor do we currently plan to establish the capability to manufacture product candidates for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We plan to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

We expect to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to comply with applicable regulations, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have nor does we currently plan to develop the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to manufacture the clinical supplies of our product candidates. We plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our drug products is not commercially feasible, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers on acceptable terms or at all;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Third-party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We may be unable to realize the potential benefits of any current or future collaboration.

We have entered into strategic collaborations and license agreements with the University of Utah, HLBLS, and CPRIT. While we may seek to enter into future collaborations for the development and commercialization of our product candidates, there can be no assurance that we will be able to do so. Even if we are successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful and we may be unable to realize in full or in part the potential benefits of any of our current collaborations.

Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;

- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

Risks Related to Commercialization of our Product Candidates

We currently have very limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although some of our employees may have marketed, launched, and sold other pharmaceutical products in the past while employed at other companies, We have no experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization

If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

We may attempt to form collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans.

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaborators and entering into agreements to develop and/or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our future revenue expectations and, assuming approval of a product candidate, our business may suffer.

Given the small number of patients who have the diseases that we are targeting, the eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. For example, based off data from the National Institute of Health (NIH) and physician collaborators, we believe that there are approximately 500 Ewing sarcoma patients diagnosed annually in the United States. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth, which would negatively affect our revenue and operating results.

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to oncology therapies and the other product candidates that we may seek to develop or commercialize in the future. The list of companies working on some form of cancer treatment is almost limitless with big and small companies working on every aspect of oncology therapies worldwide.

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in pre-clinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure of seclidemstat or other product candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Even if we obtain the necessary approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including but not limited to:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable.

We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our current product candidates would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- Our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- We may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;

- our product candidates may not succeed in pre-clinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations.

Failure to obtain or maintain adequate reimbursement or insurance coverage for products when approved to market, if any, could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford expensive treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by Centers for Medicare and Medicaid Services, ("CMS"), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as our and what reimbursement codes our product candidates may receive if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval.

Risks Related to our Business Operations

Our future success depends in part on our ability to retain our president and chief executive officer and our executive vice president of finance and chief financial officer, and to attract, retain, and motivate other qualified personnel.

We are a small company with a limited number of employees performing multiple tasks each. We are highly dependent on David J. Arthur, our president and chief executive officer, and Mark J. Rosenblum, our executive vice president of finance and chief financial officer, the loss of service from either may adversely impact the achievement of our objectives. Although Mr. Arthur's employment agreement contains a non-compete provision for a period of one year following the termination of his employment agreement, he could leave our employment at any time, as he is an “at will” employee. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. Additionally, this shortage of highly qualified personnel is particularly acute in the area where we are located. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Mr. Arthur or Mr. Rosenblum may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 8, 2023, we had 12 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Our Common Stock

The terms of the warrants could impede our ability to enter into certain transactions or obtain additional financing.

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

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

Sales of a substantial number of our shares of common stock in the public markets, or the perception that such sales could occur, including from the exercise of warrants or sales of common stock issuable thereunder, could

cause the market price of our shares of common stock to decline and impair our ability to raise capital through the sale of additional equity securities. A substantial number of shares of common stock are being offered by this prospectus. We cannot predict the number of these shares that might be sold nor the effect that future sales of our shares of common stock, including shares issuable upon the exercise of warrants, would have on the market price of our shares of common stock.

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

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

General Risks

Failure in our information technology and storage systems could significantly disrupt the operation of our business and/or lead to potential large liabilities.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology systems. Information technology systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non-public information which in turn could lead to operational difficulties and liabilities.

A security breach or privacy violation that leads to disclosure of consumer, customer, supplier, partner or employee information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue.

The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Item 1B. Unresolved Staff Comments

None.

Items 2. Properties

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

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is on the Nasdaq Capital Market under the symbol "SLRX."

[As of March 20, 2023, we had approximately 151 record holders of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these record holders.

Equity Compensation Plan Information

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

Recent Sales of Unregistered Securities

Other than as previously disclosed on our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q filed with the SEC, we did not issue any unregistered equity securities during the twelve months ended December 31, 2022.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers
None.

Item 6.

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

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings "SPECIAL NOTE REGARDING Forward-Looking Statements" and "Risk Factors" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report. These risks could cause our actual results to differ materially from any future performance suggested below.

Introduction

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

Overview

We are a clinical-stage biotechnology company focused on developing effective targeted cancer treatments for indications with high unmet medical need. Our technologies correct the dysregulated gene expression of diseased cells and thereby inhibit cancer progression. In certain cancers, the proteins that regulate gene expression become dysregulated and incorrectly turn genes “on” or “off,” which can lead to disease development and progression. We are developing two classes of drugs that address gene dysregulation: epigenetic drugs and targeted protein degraders. Our lead epigenetic enzyme technology was licensed from the University of Utah Research Foundation in 2011. In January 2022 we acquired our lead targeted protein degrader from DeuteRx.

Epigenetics refers to the system that regulates gene expression through conformational changes to the chromatin rather than changes to the DNA sequence itself. Seclidemstat (“SP-2577”), is a small molecule that inhibits the epigenetic enzyme lysine specific demethylase 1 (“LSD1”). LSD1 is an enzyme that removes mono- and di-methyl marks on histones (core protein of chromatin) to alter gene expression. LSD1’s enzymatic activity can cause genes to turn on or off and thereby affect the cell’s gene expression and overall activity. In addition, LSD1 can act via its scaffolding properties, independently of its enzymatic function, to alter gene expression and modulate cell fate. In healthy cells, LSD1 is necessary for stem cell maintenance and cell development processes. However, in several cancers LSD1 is highly expressed and acts aberrantly to incorrectly silence or activate transcription of genes leading to disease progression. High levels of LSD1 expression are often associated with aggressive cancer phenotypes and poor patient prognosis. Hence, development of targeted LSD1 inhibitors is of interest for the treatment of various cancers. SP-2577 uses a novel, reversible mechanism to effectively inhibit LSD1’s enzymatic and scaffolding properties and thereby treat and prevent cancer progression.

On October 18, 2022, the Company voluntarily paused new patient enrollment in its Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas per protocol design. The pause in new patient enrollment was due to a metastatic FET-rearranged sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). Upon review of the SUSAR and available information by the Company’s independent Safety Review Committee for the clinical trial, patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. During a conference call with the U.S. Food and Drug Administration (FDA) on November 1, 2022, the FDA informed the Company that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, the FDA informed the Company that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA’s clinical hold procedures provide the Company with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

Our first indication of interest for SP-2577 is a devastating bone and soft-tissue cancer called Ewing sarcoma. Ewing sarcoma mostly afflicts adolescents and young adults, with the median age of diagnosis being approximately 15 years of age. The most commonly expressed fusion oncoprotein in Ewing sarcoma is the EWS-FLI fusion protein, which is present in approximately 85% of Ewing sarcoma cases. The LSD1 enzyme associates with EWS-FLI (and other E26 Transformation-Specific (“ETS”) fusion proteins) and is thought to promote tumorigenesis. We believe the SP-2577 molecule helps inhibit EWS-FLI activity by disrupting EWS-FLI from associating with coregulators (including LSD1) that are necessary for its cancer promoting activity. Therefore, we believe that SP-2577 can potentially reverse the aberrant gene expression and thereby possibly prevent Ewing sarcoma cell proliferation and even promote cell death. Preclinical studies of SP-2577 in certain Ewing sarcoma animal models show a significant tumor reduction as well as a significant survival benefit compared to untreated animals. Our ongoing Phase 1/2 clinical trial is designed as a single agent dose escalation followed by a dose expansion study. The trial can enroll up to 50 relapsed or refractory Ewing sarcoma patients. The primary objectives of the study are to assess the safety and tolerability of SP-2577. Secondary objectives include assessing preliminary efficacy of SP-2577.

As LSD1 can associate with over 60 regulatory proteins other than EWS-FLI, we believe that LSD1 may also play a critical role in progression of various other cancer types. These include both solid tumors and hematologic malignancies. In the second quarter of 2019, we initiated a second company-sponsored Phase 1 trial to study SP-2577 in Advanced Solid Tumors and in the first quarter of 2022 the study was completed. The Advanced Solid Tumor (“AST”) trial was a single agent dose escalation, dose expansion study enrolling patients with advanced malignancies, excluding Ewing sarcoma or central nervous system tumors.

In addition, data from “LSD1 Ablation Stimulates Anti-tumor Immunity and Enables Checkpoint Blockade” by W. Sheng, et al. and “Inhibition of Histone Lysine-specific Demethylase 1 Elicits Breast Tumor Immunity and Enhances

Antitumor Efficacy of Immune Checkpoint Blockade" by Y. Qin, et al. suggests that LSD1 plays a role in tumor immune activity and can sensitize tumors to checkpoint inhibitors. These recent works have sparked interest in combining LSD1 inhibitors with checkpoint inhibitors.

Targeted Protein Degradation (TPD) is rapidly growing and attracting a lot of interest from the biggest pharmaceutical companies. SP-3164 is a novel, differentiated targeted protein degrader. Our plan is to develop SP-3164 in high unmet need hematological and solid tumor indications. SP-3164's development in hematological indications leverages the clinical safety and efficacy data demonstrated by avadomide in hematological malignancies (e.g., Diffuse Large B cell Lymphoma, Follicular Lymphoma) across several clinical trials. SP-3164 is the stabilized, active S-enantiomer of avadomide, which exists as a 1:1 ratio of the S and R enantiomers. However, only the S-enantiomer is the active, anticancer species. Therefore, since SP-3164 is the stabilized S-enantiomer, it has the potential to show improved therapy and safety over avadomide. SP-3164's potential has been demonstrated in in vitro studies and in preclinical mouse models of lymphoma and multiple myeloma. SP-3164 treatment showed robust anticancer activity in cells and tumored mouse models. Encouragingly, in lymphoma preclinical mouse models, treatment with SP-3164 combined with a standard of care agent resulted in complete tumor regressions.

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception. We had an accumulated deficit of $63.8 million as of December 31, 2022. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates, add personnel necessary to continue to operate as a public company, and work to develop an advanced clinical pipeline of product candidates. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of clinical development programs and efforts to achieve regulatory approval.

As of December 31, 2022, we had cash and cash equivalents of $12.1 million. We have received $16.0 million since inception of the grant. To date, our funding source have been limited to a CPRIT grant and the sale of equity securities. We believe that as of December 31, 2022, CPRIT fund matching requirements had been fully met. Additionally, during the twelve months ended December 31, 2022, we received $2.0 million cash from equity offerings.

The lack of revenue from product sales to date and recurring losses from operations since our inception raise substantial doubt as to our ability to continue as a going concern. We will continue to require substantial additional capital to continue our clinical development activities and may need such additional capital sooner than 12 months. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development, regulatory approvals and authorizations, commercialization efforts and market conditions. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop and commercialize our product candidates.

We intend to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments. We may also consider new collaborations or selectively partnering our technology. However, we cannot provide any assurance that we will be successful in accomplishing any of our plans to obtain additional capital or be able to do so on terms acceptable to us.

Results of Operations

The following table sets forth the consolidated results of our operations for the year ended December 31, 2022 compared to the year ended December 31, 2021.

	Year ended December 31		Change
	2022	2021	$
Grant revenue	$ —	$ 1,840,216	$ (1,840,216)
Research and development expenses	15,836,828	8,548,520	7,288,308
General and administrative expenses	7,138,403	6,104,627	1,033,776
Change in fair value of warrant liability	14,454	44,693	(30,239)
Interest income (expense), net	218,730	—	218,730
Loss on impairment of goodwill	8,865,909	—	8,865,909
Net loss	$ (31,607,956)	$ (12,768,238)	$ (18,839,718)

Grant Revenue

Grant revenue, which was derived solely from the CPRIT grant, was $0 during the year ended December 31, 2022 compared to $1.8 million during the year ended December 31, 2021. We reached the maximum amount of the eligible spending that can be reimbursed from CPRIT in 2021. In February 2023, we received $1.5 million from CPRIT, a collection of an outstanding receivable at December 31, 2022.

Research and Development Expenses

Research and development expenses were $15.8 million during the year ended December 31, 2022 compared to $8.5 million during the year ended December 31, 2021. This increase of $7.3 million principally resulted from the purchase of the DeuteRx assets in January 2022, and the development of those assets (the most advanced of which is known as SP-3164) during 2022, that was partially offset by lower cost related to SP-2577.

	SP - 3164		SP- 2577	
Research and development costs by candidates and by categories:	**2022**	**2021**	**2022**	**2021**
Outsourced research and development costs	$ 3,832,805	$ —	$ 4,797,053	$ 4,980,444
Employee-related costs	182,109	—	2,157,338	1,604,505
Manufacturing and laboratory costs	2,170,682	—	708,941	1,963,571
Purchased in process research and development costs	1,987,900	—	—	—
Total research and development costs	**$ 8,173,496**	**$ —**	**$ 7,663,332**	**$ 8,548,520**

General and Administrative Expense

General and administrative expenses were $7.1 million for the year ended December 31, 2022 compared to $6.1 million for the year ended December 31, 2021, the increase is mainly driven by higher legal cost, public company cost and personnel costs.

Liquidity and Capital Resources

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for the foreseeable future. To date, we have generated revenue from the CPRIT grant, and have not generated any cash inflows from product sales.

We have known material contractual obligations which will require cash to meet their requirements. These applicable obligations include our lease agreement for our facilities, and our employment contracts. We also plan to deploy cash for other research and development and general and administrative operating expenses. Our ability to continue meeting these contractual obligations will be reliant upon our ability to secure significant additional capital funding.

We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercializes any of our product candidates, all of which are in early stages of development. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for our product candidates.

As of December 31, 2022, we had $10.3 million of working capital and our cash and cash equivalents totaled $12.1 million, which were held in bank accounts and money market account. Our cash and cash equivalents balance decreased during the year ended December 31, 2022, primarily due to the cash used in operating and investing activities, partially offset by capital received from financing activities. We believe that our cash and cash equivalents on hand as of December 31, 2022 is sufficient to fund our anticipated operations through the third quarter of 2023.

Liquidity

	Year Ended December 31	
	2022	**2021**
Net cash (used in) provided by:		
Operating activities	$ (17,595,321)	$ (10,200,197)
Investing activities	(1,500,000)	—
Financing activities	1,987,376	28,295,963
Net increase (decrease) in cash and cash equivalents	$ (17,107,945)	$ 18,095,766

	Year Ended December 31	
	2022	**2021**
Net proceeds from issuance of equity securities	1,987,376	27,287,638
Payments on note payable	—	(477,028)
Net proceeds from warrants exercised for cash	—	1,485,353
Net cash provided by financing activities	**$ 1,987,376**	**$ 28,295,963**

Capital Resources

We expect to continue to incur additional costs associated with our ongoing research and development activities and our continued operation as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we anticipate we will need substantial additional funding in connection with our continuing operations.

We have no products approved for commercial sale, have not generated any revenue from product sales to date and have suffered recurring losses from operations since our inception. The lack of revenue from product sales to date and recurring losses from operations since our inception raise substantial doubt as to our ability to continue as a going concern. Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Based on our expected cash requirements, we believe that there is substantial doubt that our existing cash and cash equivalents will be sufficient to fund our operation through one year from the date of this report.

We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates in or towards clinical development.

Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- our ability to have the partial clinical hold that has been placed on our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas lifted and the timing thereof;

- the terms and timing of any strategic alliance, licensing and other arrangements that we may establish;
- the initiation and progress of our ongoing pre-clinical studies and clinical trials for our product candidates;
- the number of programs we pursue;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of our product candidates manufactured.

We expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowing, strategic alliances with partner companies, and grants. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market itself.

Successful development of product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate and ongoing assessments as to each product candidate’s commercial potential. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

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

Our significant accounting policies are described in Note 2 to our audited consolidated financial statements for the year ended December 31, 2022 in this Annual Report on Form 10-K. We believe that our accounting policies relating to revenue recognition, research and development expenses, stock-based compensation and fair value of financial instruments are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they both are important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. For more information regarding these policies, you should refer to Note 2 of our audited consolidated financial statements included in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

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

Application of New Accounting Standards

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. The guidance eliminates certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. This guidance also includes guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for annual and interim periods in fiscal years beginning after December 15, 2020. The adoption of ASU 2019-12 in the first quarter of 2021 did not have a material impact on the Company's consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

SALARIUS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Salarius Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Salarius Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has a lack of revenue from product sales and has suffered recurring losses from operations since its inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Accrued Research and Development Expenses

Description of the Matter	During 2022, the Company recognized $15.8 million of research and development expenses and recorded accrued clinical trial expenses of $0.4 million as of December 31, 2022. As described in Note 2 to the consolidated financial statements, the Company records accruals for estimated costs of research and development activities that include contract services for clinical trials. Clinical trial activities performed by third parties are accrued and expensed based upon management's assessment of the status of each clinical trial and the work completed per patient. Auditing the Company's accounting for accrued third-party clinical trial research and development expenses is especially challenging because of the judgment applied by management to determine the progress or stage of completion of the activities under the Company's research and development agreements and the cost and extent of work performed during the reporting period for services not yet billed by contracted third-party vendors.
How We Addressed the Matter in Our Audit	Our audit procedures included, among others, testing the accuracy and completeness of the underlying inputs used in management's analysis to determine costs incurred, inspecting invoices received from third parties, and clerically testing the accrual calculation. To test the significant inputs, we corroborated the patient enrollment, length of treatment, trial timeline and progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects, inspected the terms and conditions of the Company's contracts with third parties, and obtained external confirmation of key inputs to the accrual calculation, such as amounts invoiced and the number and timing of patients enrolled in clinical studies. We also reviewed subsequent disbursements for payments made to third parties after the balance sheet date to evaluate the completeness of the research and development expenses recognized.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2019.
Houston, Texas
March 27, 2023

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 12,106,435	$ 29,214,380
Grants receivable from CPRIT	1,610,490	—
Prepaid expenses and other current assets	803,373	949,215
Total current assets	14,520,298	30,163,595
Grants receivable from CPRIT	—	1,610,490
Goodwill	—	8,865,909
Other assets	130,501	193,874
Total assets	$ 14,650,799	$ 40,833,868
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,858,330	$ 1,543,096
Accrued expenses and other current liabilities	1,407,861	567,787
Total liabilities	$ 4,266,191	$ 2,110,883
Commitments and contingencies (NOTE 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; none issued or outstanding	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized; 2,255,899 and 1,809,593 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	225	181
Additional paid-in capital	74,189,531	70,919,996
Accumulated deficit	(63,805,148)	(32,197,192)
Total stockholders' equity	10,384,608	38,722,985
Total liabilities and stockholders' equity	$ 14,650,799	$ 40,833,868

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31	
	2022	**2021**
Revenue:		
Grant revenue	$ —	$ 1,840,216
Operating expenses:		
Research and development	15,836,828	8,548,520
General and administrative	7,138,403	6,104,627
Loss on impairment of goodwill	8,865,909	—
Total operating expenses	31,841,140	14,653,147
Loss before other income (expense)	(31,841,140)	(12,812,931)
Change in fair value of warrant liability	14,454	44,693
Interest income	218,730	
Net loss	$ (31,607,956)	$ (12,768,238)
Loss attributable to common stockholders	$ (31,607,956)	$ (12,768,238)
Loss per common share — basic and diluted	$ (14.88)	$ (7.72)
Total net loss per share	$ (14.88)	$ (7.72)
Weighted-average number of common shares outstanding — basic and diluted	2,124,511	1,654,638

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Twelve Months Ended December 31	
	2022	**2021**
Operating activities		
Net loss	$ (31,607,956)	$ (12,768,238)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and impairment	6,677	19,183
Loss on Impairment of goodwill	8,865,909	—
Equity-based compensation expense	796,803	559,044
Change in fair value of warrant liability	(14,454)	(44,693)
In-process research and development technology	1,987,900	—
Changes in operating assets and liabilities:		
Grants receivable	—	2,245,506
Prepaid expenses and other current assets	202,538	(70,470)
Accounts payable	1,312,735	(310,660)
Accrued expenses and other current liabilities	854,527	170,131
Net cash (used in) operating activities	(17,595,321)	(10,200,197)
Investing activities		
Purchase in-process research and development technology	(1,500,000)	—
Net cash used in investing activities	(1,500,000)	—
Financing activities		
Proceeds from issuance of equity securities	1,987,376	27,287,638
Proceeds from warrants exercised for cash	—	1,485,353
Payments on note payable	—	(477,028)
Net cash provided by financing activities	1,987,376	28,295,963
Net (decrease) increase in cash, cash equivalents and restricted cash	(17,107,945)	18,095,766
Cash, cash equivalents and restricted cash at beginning of period	29,214,380	11,118,614
Cash, cash equivalents and restricted cash at end of period	$ 12,106,435	$ 29,214,380
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 1,468
Non-cash investing and financing activities:		
Common stock issued for in-process research and development technology	$ 487,900	$ —
Accrued cost for shares issued for cash	$ 2,500	

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2020	**952,341**	**$ 95**	**$ 41,588,047**	**$ (19,428,954)**	**$ 22,159,188**
Issuance of equity securities, net	802,182	81	27,287,557	—	27,287,638
Warrants exercised for cash	51,943	5	1,485,348	—	1,485,353
Equity-based compensation expense	2,958	—	559,044	—	559,044
Issuance of equity securities for services	169	—	—	—	—
Net loss	—	—	—	(12,768,238)	(12,768,238)
Balance at December 31, 2021	**1,809,593**	**$ 181**	**$ 70,919,996**	**$ (32,197,192)**	**$ 38,722,985**
Common Stock issued for in-process research and development technology	40,000	4	487,896	—	487,900
Issuance of equity securities, net	373,577	37	1,984,839	—	1,984,876
Equity-based compensation expense	27,927	3	768,252	—	768,255
Issuance of equity securities for services	4,802	—	28,548	—	28,548
Net loss	—	—	—	(31,607,956)	(31,607,956)
Balance at December 31, 2022	**2,255,899**	**$ 225**	**$ 74,189,531**	**$ (63,805,148)**	**$ 10,384,608**

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND OPERATIONS

Nature of Business

Salarius Pharmaceuticals, Inc. (“Salarius” or the “Company”), together with its subsidiaries, Salarius Pharmaceuticals, LLC, Flex Innovation Group LLC, and TK Pharma, Inc., is a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, the Company is developing treatments for cancers caused by dysregulated gene expression, i.e., genes that are incorrectly turned on or off. The Company is developing two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. The Company's technologies have the potential to work in both liquid and solid tumors. The Company's current pipeline consists of two small molecule drugs: 1) SP-3164, a targeted protein degrader, and 2) seclidemstat (SP-2577), a targeted protein inhibitor. The Company is located in Houston, Texas. In addition, the company has early stage development in both protein inhibition and protein degradation.

Going Concern

Salarius has no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Salarius will require substantial additional capital to fund its research and development expenses related to its oncology drug. Based on Salarius’ expected cash requirements, Salarius believes that there is doubt that its existing cash and cash equivalents, will be sufficient to fund its operations through one year from the financial statements issuance date. The Company intends to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

Acquisition and Strategic Collaboration Agreement

On January 12, 2022, the Company, entered into an Acquisition and Strategic Collaboration Agreement (the “ASCA”), with DeuteRx, LLC, a Delaware limited liability company (the “DeuteRx”), pursuant to which DeuteRx agreed to sell, and the Company agreed to purchase and assume from DeuteRx, all of DeuteRx’s rights, title, and interest in and to certain assets of DeuteRx, including SP-3164, DeuteRx’s intellectual property, information and data related to SP-3164, tangible materials or reagents related to SP-3164, goodwill, rights and claims, other than certain excluded assets (collectively, the “Purchased Assets”), all as more specifically set forth in the ASCA, and assume certain assumed liabilities, upon the terms and subject to the conditions set forth in the ASCA. The Aggregate purchase price paid under the ASCA was $2.0 million consisting of $1.5 million cash payment and the delivery of 40,000 shares of the Company's common stock, valued at $0.5 million. Total cost incurred in obtaining in-process research and development technology ("IPRD") that has no alternative future use are charged to research and development expense as acquired, and presented as investing activity cash outflow on the Statement of Cash Flow. In addition, the Company agreed to pay to DeuteRx potential future milestone payments upon the occurrence of an applicable Milestone Event (as defined in the ASCA) and potential future royalty payments. A member of the Company’s Board of Directors also serves as a consultant to DeuteRx and is employed by an affiliate of DeuteRx.

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to

refer to the authoritative GAAP as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The Company considered its going concern disclosure requirements in accordance with ASC 205-40-50.The Company has performed an analysis and concluded substantial doubt exists with respect to the Company being able to continue as a going concern through one year from the date of issuance of the consolidated financial statements for the year ended December 31, 2022.

Principles of Consolidation

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

Use of Estimates

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

Reclassification

Certain reclassifications of prior period presentations have been made to conform to the current period presentation.

Cash and Cash Equivalents

Salarius considers all highly-liquid investments with original maturities of three months or less to be cash equivalents.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment charges related to long-lived assets during the twelve months ended December 31, 2022 and 2021.

Goodwill

Goodwill is not amortized, but is tested at least annually for impairment at the reporting unit level. The Company has determined that the reporting unit is the single operating segment disclosed in its current financial statements. Additional impairment assessments may be performed on an interim basis if the Company encounters events or changes in circumstances that would indicate that, more likely than not, the carrying value of goodwill has been impaired.

Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The Company utilizes the option to perform a qualitative assessment for its reporting unit and if the Company concludes it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company utilizes the two-step quantitative assessment. The Company's qualitative assessment is sensitive to assumptions related to potential adverse events and circumstances, including current market trends in control premiums and involves judgement in determining comparable peer companies to include in the control premium evaluation. The Company recorded goodwill impairment loss of $8.9 million and $0 million during the twelve months ended December 31, 2022 and 2021, respectively .

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and restricted cash. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation ("FDIC"). Although the balances in these

accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Warrants

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

Clinical Trial Accruals

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

Grants Receivable and Revenue Recognition

Salarius' source of revenue has been from a grant received from CPRIT. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. The Company records revenue and a corresponding grants receivable when qualifying costs are incurred before the grants are received.

Research and Development Costs

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

Costs incurred in obtaining IPRD that has no alternative future use are charged to research and development expense as acquired, and presented as investing activity cash outflows on the Statement of Cash Flow.

Equity-Based Compensation

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

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

Loss Per Share

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

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, (iii) unvested restricted stock and (iv) rights entitling holders to receive warrants to purchase the Company's common shares, which have been excluded from the computation of diluted loss per share, was 704,640 and 381,248 shares as of December 31, 2022 and 2021, respectively.

Income Taxes

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

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2022 and 2021, the Company did not have any significant uncertain tax positions and no interest or penalties have been charged. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company is subject to routine audits by taxing jurisdictions.

Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement of all expected credit losses for financial assets including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses*. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 842)*, which did not change the core principle of the guidance in ASU 2016-13 but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. Early adoption is permitted. As a smaller reporting company, the guidance will be effective for the Company during the first quarter of 2023. The Company is in the process of assessing the impact adoption will have on its consolidated financial statements.

NOTE 3. GRANTS RECEIVABLE

Grants receivable represents qualifying costs incurred where there is reasonable assurance that conditions of the grant have been met but the corresponding funds have not been received as of the reporting date. Grants receivable balances were $1.6 million as of December 31, 2022 and December 31, 2021, respectively. Grant receivables are classified as current or non-current receivables based on the Company's best estimate of whether or not the amounts will be collected within one year of the balance sheet date. The Company received $1.5 million from the Cancer Prevention and Research Institute of Texas on February 15, 2023.

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Prepaid clinical trial expenses	$ 11,185	$ 97,557
Prepaid insurance	624,612	678,672
Other prepaid and current assets	167,576	172,986
Total prepaid expenses and other current assets	$ 803,373	$ 949,215

Prepaid insurance is mainly comprised of prepaid directors' and officers' insurance.

NOTE 5. COMMITMENTS AND CONTINGENCIES

License Agreement with the University of Utah Research Foundation

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

Cancer Prevention and Research Institute of Texas

In June 2016, the Company entered into a Cancer Research Grant Contract with CPRIT. Pursuant to the contract, CPRIT awarded the Company a grant up to $18.7 million, further modified to $16.1 million to fund development of LSD 1 inhibitor. This is a 3-year grant award originally expired on May 31, 2019. The grant now expires on May 31, 2023. The Company applied for a no cost extension through November 30, 2023.

The Company will retain ownership over any intellectual property developed under the contract ("Project Result"). With respect to non-commercial use of any Project Result, the Company agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

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

Lease Agreement

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

6. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

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

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

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

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

7. STOCKHOLDERS' EQUITY

Preferred Stock and Common Stock

On October 14, 2022, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a 1-for-25 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split"), which became effective on October 14, 2022. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

Common Stock Issuances

On January 12, 2022, the Company issued 40,000 shares of the Company's common stock, valued at $0.5 million to purchase in-process research and development technology SP-3164, please refer to NOTE 1 for further discussion.

On April 22, 2022, the Company entered into a securities purchase agreement with certain institutional and accredited investors for the sale by the Company of approximately 373,577 shares of the Company's common stock, par value $0.0001 per share (the "Common Stock") at a purchase price of $6.25 per share. Concurrently, the Company also sold unregistered warrants exercisable for an aggregate of approximately 280,183 shares of Common Stock, which represents 75% of the shares of Common Stock sold, with an exercise price of $ 8.4975 per share. The transaction closed on April 26, 2022 with gross proceeds of $2.3 million before deducting certain fees due to the placement agent and other estimated transaction expenses.

On February 5, 2021, the Company entered into an At the Market Offering Agreement ("ATM") with Ladenburg Thalmann & Co. Inc. Under this agreement the Company is able to issue and sell, from time to time, shares of its common stock. On February 5, 2021 and July 2, 2021, the Company filed prospectus supplements with the SEC to register the offering and sale of Common Stock having an aggregate offering price of up to $6.3 million and $25.0 million, respectively. During the twelve months ended December 31, 2021, the Company issued 3,247,834 shares under the ATM for gross proceeds of $6.8 million.

On March 8, 2021, the Company completed a public offering of 672,269 shares of its common stock at a price to the public of $34.21 per share. Total gross proceeds from the offering were approximately $23.0 million prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

Warrants Exercised for Cash

The Company has five-year warrants outstanding that were issued in February 2020 and subsequently modified in December 2020 in connection with the issuance of additional inducement warrants. The warrants are exercisable at a price per share of $28.75. The inducement warrants expire on June 11, 2026 and are exercisable at a price per share of $29.55. The Company has 5.5 year warrants issued on April 2022, with an exercise price of $8.4975 per share. The warrants will be exercisable six months following the issuance date and will expire five and one-half years from the issuance date.

During the twelve months ended December 31, 2022, no warrants were exercised. During the twelve months ended December 31, 2021, the Company issued approximately 51,943 common shares as a result of warrant exercises, and received cash proceeds of approximately $1.5 million, respectively.

The Company has 597,512 and 317,329 warrants outstanding at year ended December 31, 2022 and 2021, respectively.

8. EQUITY-BASED COMPENSATION

Equity Incentive Plans

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards may be granted to the Company's employees, including officers, and to non-employee directors and consultants. As of December 31, 2022 and 2021, there were 47,228 and 41,068 shares, respectively, remaining available for the grant of stock option under the 2015 Plan.

During the twelve months ended December 31, 2022 and 2021, the Company awarded 51,360 and 3,160, respectively, stock options to its employees and directors, pursuant to the plan described above. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants of $0.5 million and $0.1 million respectively, has been estimated with the following assumptions for the year ended December 31, 2022 and 2021:

	2022	2021
Risk-free interest rate	1.62%-1.70%	0.93%-1.09%
Volatility	125.19% - 126.42%	130.44%-133.35%
Expected life (years)	5 -6 years	6 years
Expected dividend yield	0.00%	0.00%

The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2022 and 2021:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	62,559	$ 69.50	4.87	$ 175,770
Granted	3,160	32.50		
Exercised	—	—		
Forfeited	(1,800)	—		
Expired	—	—		
Outstanding at December 31, 2021	63,919	$ 68.75	8.50	$ —
Exercisable at December 31, 2021	27,334	$ 121.25	8.21	$ —
Granted	51,360	$ 10.95		
Exercised	—			
Forfeited	(6,776)			
Expired	(1,375)			
Outstanding at December 31, 2022	107,128	$ 23.67	8.29	$ —
Exercisable at December 31, 2022	38,100	$ 35.85	7.63	$ —

As of December 31, 2022 and 2021, there was approximately $0.8 million and $0.9 million of total unrecognized compensation cost, respectively, related to unvested stock options. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.13 years.

During the year ended December 31, 2021, the Company granted 3,160 stock options, in the aggregate, to certain employees. These awards vest monthly over 4 years as continuous services are provided, and expense is being recognized over this period. Total compensation cost related to stock options was $0.5 million for the year ended December 31, 2021.

During the year ended December 31, 2022, the Company granted 51,360 stock options, in the aggregate, to certain employees and directors. These awards vest over 1 year to 4 years as continuous services are provided, and expense is being recognized over this period. Total compensation cost related to stock options was $0.5 million for the year ended December 31, 2022

During the year ended December 31, 2022 and 2021, the Company granted 9,712 and 2,958 shares of common stock to its Employee Stock Purchase Plan ("ESPP") participants. Fair value of the grants are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the derived service period.

9. INCOME TAX

The Company has no current or deferred tax expense due to its current year loss and its overall net operating loss position. A reconciliation of the federal statutory tax rate and the effective tax rates for the year ended December 31, 2022 and 2021 is as follows:

	December 31	
	2022	2021
Federal Tax at Statutory Rate	21.00%	21.00%
Permanent	(6.25)%	(0.69)%
Change in Valuation Allowance	(21.73)%	(26.13)%
True Ups	(0.06)%	—%
R&D Credit	7.04%	5.82%
Effective Tax Rate	—%	—%

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

	December 31	
	2022	2021
Capitalized R&D Expenses	$ 5,199,721	$ 3,002,819
Other Deferred Items	145,935	121,152
Stock Compensation	484,205	50,650
Net Operating Loss - US	3,919,323	1,931,959
R&D Credits	3,293,572	1,068,451
Net deferred tax assets	13,042,756	6,175,031
Valuation Allowance	(13,042,756)	(6,175,031)
Net deferred tax assets (liabilities)	**$ —**	**$ —**

The valuation allowance recorded by the Company as of December 31, 2022 and December 31, 2021 resulted from the uncertainties of the future utilization of deferred tax assets relating from NOL carry forwards for federal and state income tax purposes. Realization of the NOL carry forwards is contingent on future taxable earnings. The deferred tax asset was reviewed for expected utilization using a “more likely than not” approach by assessing the available positive and negative evidence surrounding its recoverability. Accordingly, a full valuation allowance continues to be recorded against the Company’s deferred tax asset, as it was determined based upon past and projected future losses that it was “more likely than not” that the Company’s deferred tax assets would not be realized. In future years, if the deferred tax assets are determined by management to be “more likely than not” to be realized, the recognized tax benefits relating to the reversal of the valuation allowance will be recorded. The Company will continue to assess and evaluate strategies that will enable the deferred tax asset, or portion thereof, to be utilized, and will reduce the valuation allowance appropriately as such time when it is determined that the “more likely than not” criteria is satisfied.

The federal net operating loss carryforwards of $18.6 million have an indefinite life, but the R&D credits of $3.2 million begin to expire in 2039. Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company’s net operating loss carry forwards could be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carry forwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

Tax positions taken or expected to be taken in the course of preparing the Company’s tax returns are required to be evaluated to determine whether the tax positions are “more-likely-than-not” of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold, as well as accrued interest and penalties, if any, would be recorded as an interest and penalties expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2022.

The Tax Cuts and Jobs Act of 2017 (TCJA) has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company must now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Since this has been the Company's policy since 2019, the current year capitalization of research and development costs in accordance with IRC 174 was $13.4 million for a total accumulated gross amount of $24.7 million as of December 31, 2022.

10. SUBSEQUENT EVENTS

On February 15, 2023, the Company received $1.5 million from the Cancer Prevention and Research Institute of Texas. The payment is part of a non-dilutive grant of approximately $16.1 million awarded to support operations and development of the Company's drug candidate seclidemstat for the treatment of Ewing sarcoma. The $1.5 million payment brings the Company's cumulative disbursement from CPRIT to approximately $16.0 million.

From January 27, 2023 through March 24, 2023, the Company sold 142,499 shares of its common shares with gross proceeds of approximately $0.4 million pursuant to its at the-market equity offering program.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As of December 31, 2022, our management, including our principal executive officer and principal financial officer, had evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) pursuant to Rule 13a-15(b) under the Exchange Act. Based upon and as of the date of the evaluation, our principal executive officer and principal financial officer concluded that information required to be disclosed is recorded, processed, summarized and reported within the specified periods and is accumulated and communicated to management, including our principal executive officer and principal financial officer, to allow for timely decisions regarding required disclosure of material information required to be included in our periodic SEC reports. Based on the foregoing, our management determined that our disclosure controls and procedures were effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

No change in our company’s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the framework in Internal Control—Integrated Framework 2013 issued by the

Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Item 9B. Other Information

None

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2023 annual meeting of stockholders, pursuant to Regulation 14A of the Exchange Act of 1934, also referred to in this Annual Report on Form 10-K as our 2023 Proxy Statement, which we expect to file with the SEC no later than May 1, 2023.

Item 10. Directors, Executive Officers and Corporate Governance

Corporate Governance

We have adopted a written Code of Business Conduct that applies to all of our employees, officers and directors. This Code of Business Conduct is designed to ensure that our business is conducted with integrity and in compliance with SEC regulations and Nasdaq listing standards. The Code of Business Conduct covers adherence to laws and regulations as well as professional conduct, including employment policies, conflicts of interest and the protection of confidential information. The Code of Business Conduct is available under “Governance Overview” within the “Corporate Governance” section of our website at www.salariuspharma.com.

We intend to disclose any future amendments to, or waivers from, the Code of Business Conduct that affect our directors or senior financial and executive officers within four business days of the amendment or waiver by posting such information on the website address and location specified above.

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2023 Proxy Statement.

Item 11. Executive Compensation

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2023 Proxy Statement.

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

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2023 Proxy Statement.

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

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2023 Proxy Statement.

Item 14. Principle Accounting Fees and Services

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2023 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements on page 63.

(a)(2) Financial Statement Schedules.

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

(a)(3) Exhibits.

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Amended and Restated Certificate Amended and Restated Certificate of Incorporation of the Registrant Incorporation of the Registrant		8-K	001-36812 Exhibit 3.1	02/09/2015
3.2	Certificate of Amendment of Certificate of Incorporation of the Registrant filed with the Secretary of State of Delaware on July 18, 2019		8-K	001-36812 Exhibit 3.1	07/22/2019
3.3	Certificate of Amendment of Certificate of Incorporation of the Registrant filed with the Secretary of State of Delaware on October 14, 2022		8-K	001-36812 Exhibit 3.2	07/22/2019
3.4	Amended and Restated Bylaws of the Registrant, effective July 19, 2019		8-K	001-36812 Exhibit 3.2	07/22/2019
3.5	Amendment to Amended and Restated Bylaws of the Registrant, effective April 1, 2022		8-K	001-36813 Exhibit 3.1	04/01/2022
4.1	Form of Common Stock Certificate of Registrant		S-1	333-201276 Exhibit 4.1	12/29/2014
4.2	Form of Common Stock Purchase Form of Common Stock Purchase Warrant		S-1/A	333-235879 Exhibit 4.8	02/06/2020
4.3	Common Stock Purchase Warrant dated February 11, 2020		8-K	001-36812 Exhibit 4.1	02/12/2020
4.4	Form of Inducement Warrant dated December 11, 2020		8-K/A	001-36812 Exhibit 4.1	12/11/2020
4.5	Form of 2021 Flex Warrants		8-K	001-36812 Exhibit 4.1	07/01/2021
4.6	Form of Common Stock Purchase Warrant dated April 26, 2022		8-K	001-36812 Exhibit 4.1	04/22/2022
4.7	Description of Registrant's Securities		10-K	001-36812 Exhibit 4.11	03/18/2021
10.1+	Form of Indemnification Agreement between the Registrant and its directors and officers		8-K	001-36812 Exhibit 10.1	07/22/2019
10.2*	Exclusive License Agreement, dated August 3, 2011, between the University of Utah Research Foundation and Salarius Pharmaceuticals, LLC		S-4	333-229666 Exhibit 10.1	02/14/2019

10.3*	Cancer Research Grant Contract, dated June 1, 2016, between the Cancer Prevention and Research Institute of Texas and Salarius Pharmaceuticals, LLC		S-4	333-229666 Exhibit 10.3	02/14/2019
10.4+	Amended and Restated Executive Employment Agreement, dated February 5, 2019, between David J. Arthur and Salarius Pharmaceuticals, LLC		S-4	333-229666 Exhibit 10.5	02/14/2019
10.5+	Amendment to Amended and Restated Executive Employment Agreement dated September 10, 2019, among David J. Arthur, the Registrant and Salarius Pharmaceuticals, LLC		8-K	001-36812 Exhibit 10.5	09/16/2019
10.6+	Employment Agreement between Mark J. Rosenblum and Salarius Pharmaceutical, Inc., dated April 24, 2020		8-K	001-36812 Exhibit 10.1	4/29/2020
10.7+	Salarius Pharmaceuticals, Inc., 2015 Equity Incentive Plan, as amended		8-K	001-36812 Exhibit 10.1	06/19/2020
10.8+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Plan		10-K	001-36812 Exhibit 10.4	03/24/2015
10.9+	Salarius Pharmaceuticals, Inc., 2015 Employee Stock Purchase Plan, as amended		8-K	001-36812 Exhibit 10.2	06/19/2020
10.10	At the Market Offering Agreement, dated February 5, 2021, between Salarius Pharmaceuticals, Inc. and Ladenburg Thalmann & Co. Inc.		8-K	001-36812 Exhibit 1.1	02/05/2021
10.11	Securities Purchase Agreement, dated April 22, 2022		8-K	001-36812 Exhibit 10.1	04/22/2022
21.1	Subsidiaries of the Registrant		S-1	333-235879 Exhibit 21	01/10/2020
23.1	Consent of Ernst & Young LLP	X			
24.1	Power of attorney (included on Signature Page)	X			
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Schema Document	X			
101.CAL	XBRL Calculation Linkbase Document	X			
101.DEF	XBRL Definition Linkbase Document	X			
101.LAB	XBRL Label Linkbase Document	X			
101.PRE	XBRL Presentation Linkbase Document	X			

104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Portions of this exhibit have been omitted and provided separately to the SEC pursuant to a request for confidential treatment.

\+ Management contract or compensatory plans or arrangements.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

March 27, 2023 SALARIUS PHARMACEUTICALS, INC.

By: /s/ David J. Arthur
David J. Arthur
President & Chief Executive Officer

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

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

SIGNATURE	***TITLE***	***DATE***
/s/ William K. McVicar *William K. McVicar*	*Chairman of the Board*	*March 27, 2023*
/s/ David J. Arthur *David J. Arthur*	*Director, President & Chief Executive Officer (Principal Executive Officer)*	*March 27, 2023*
/s/ Mark J. Rosenblum *Mark J. Rosenblum*	*Executive Vice President of Finance and Chief Financial Officer*	*March 27, 2023*
/s/ Tess Burleson *Tess Burleson*	*Director*	*March 27, 2023*
/s/ Arnold Hanish *Arnold Hanish*	*Director*	*March 27, 2023*
/s/ Paul Lammers *Paul Lammers*	*Director*	*March 27, 2023*
/s/ Jon Lieber *Jon Lieber*	*Director*	*March 27, 2023*
/s/ Bruce McCreedy *Bruce McCreedy*	*Director*	*March 27, 2023*

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

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

of our report dated March 23, 2023, with respect to the consolidated financial statements of Salarius Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Salarius Pharmaceuticals, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Houston, Texas
March 27, 2023

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

I, David J. Arthur, certify that:

1. I have reviewed this annual report on Form 10-K of Salarius Pharmaceuticals, Inc. for the year ended December 31, 2022;
2. based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. the registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. the registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 27, 2023

By: /s/ David J. Arthur
Name: David J. Arthur
Title: Chief Executive Officer
(Principal Executive Officer)

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

I, Mark Rosenblum, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Salarius Pharmaceuticals, Inc.;
2. based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. the registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. the registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 27, 2023

By: /s/ Mark Rosenblum
Name: Mark Rosenblum
Title: Executive Vice President of Finance
and Chief Financial Officer

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

In connection with the Annual Report on Form 10-K for the year ended December 31, 2022 of Salarius Pharmaceuticals, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Arthur, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: March 27, 2023

By: /s/ David J. Arthur
Name: David J. Arthur
Title: Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report on Form 10-K for the year ended December 31, 2022 of Salarius Pharmaceuticals, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Rosenblum, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: March 27, 2023

By: /s/ Mark Rosenblum
Name: Mark Rosenblum
Title: Executive Vice President of Finance and Chief Financial Officer