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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**

For the fiscal year ended December 31, 2019

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.

(previously known as Flex 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 J 608, Houston, TX 77021
(Address of principal executive offices)(Zip Code)

Registrant's Telephone Number, Including Area Code**: (346) 772-0346**
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 is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes ☐ No ☒
The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant is $9,203,679 based on a share price of $.6995 which is the closing price per share on March 16, 2020.

As of March 16, 2020, there were 13,666,453 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:
Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SALARIUS PHARMACEUTICALS, INC.

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EXPLANATORY NOTE

On July 19, 2019, Salarius Pharmaceuticals, Inc. (formerly known as Flex Pharma, Inc.), or the Company, completed the merger (the "Merger") of its wholly owned subsidiary, Falcon Acquisition Sub, LLC ("Merger Sub"), with and into Salarius Pharmaceuticals, LLC ("Private Salarius"), in accordance with the terms of the Agreement and Plan of Merger, dated January 3, 2019, among the Company, Merger Sub and Private Salarius (as amended, the "Merger Agreement"). As a result of the Merger, Private Salarius, the surviving company in the Merger, became a wholly owned subsidiary of the Company. Following the Merger, the business of Private Salarius became the business of the Company and the Company's corporate name was changed from Flex Pharma, Inc. to Salarius Pharmaceuticals, Inc.

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally acceptable accounting principles in the United States ("U.S. GAAP") and Private Salarius is considered the accounting acquirer. Accordingly, Private Salarius' historical results of operations will have replaced the Company's historical results of operations for all periods prior to the Merger.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information in this Annual Report on Form 10-K, including in the sections entitled "Business," and "Management's Discussion and Analysis of Financial Condition and Results of Operations Overview," and the information incorporated herein by reference, include 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. These are statements that include, but are not limited to, statements about future periods; the Company's strategy and ongoing development programs; the Company's clinical trials, including status, costs and expectations related thereto; the Company's strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; the potential for Seclidemstat to target the epigenetic dysregulation underlying Ewing sarcoma and advanced solid tumors including, but not limited to, prostate, breast, ovarian, melanoma, colorectal and other cancers; expected timing and results of clinical studies; the nature, strategy and focus of the company; the development and commercial potential of any product candidates; the Company's liquidity position and need for additional financing; the ability of the Company to access additional financing under the Grant Contract with Cancer Prevention and Research Institute of Texas; and the Company's ability to continue as a going concern. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties, including those discussed under "Risk Factors," that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. When used in this report, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should," "would," "aim," "target" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, our results could differ materially from the forward-looking statements in this report. All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events.

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. In addition, the word "Flex Pharma" refers to Salarius Pharmaceuticals, Inc. 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 biotechnology company focused on developing effective epigenetic-based cancer treatments for indications with high unmet medical need. Epigenetics refers to the system that regulates gene expression through conformational changes to the chromatin rather than changes to the DNA sequence itself. Salarius' lead compound, Seclidemstat ("SP-2577"), is a small molecule, administered orally, that inhibits the epigenetic enzyme lysine specific demethylase 1 ("LSD1"). SP-2577 and related compounds were licensed from the University of Utah Research Foundation in 2011. LSD1 is an enzyme that removes mono- and di-methyl marks on histones (the core protein components 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 remodel chromatin and alter gene expression, modulating 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 genes leading to disease progression. High levels of LSD1 expression are often associated with aggressive cancer phenotypes and poor patient prognosis. In addition, 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. Hence, there has been interest in developing targeted LSD1 inhibitors for treatment of various cancers alone and/or in combination with other approved agents, such as checkpoint inhibitors.

Recent Events

On February 11, 2020, the Company completed a public offering with total gross proceeds of approximately $11.0 million, which includes the full exercise of the underwriter's over-allotment option to purchase an additional 1,252,173 shares and warrants prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius. The offering is comprised of 7,101,307 Class A units, priced at a public offering price of $1.15 per unit, with each unit consisting of one share of common stock and a five-year warrant to purchase one share of common stock at an exercise price of $1.15 per share, and 1,246,519 Class B units, priced at a public offering price of $1.15 per unit, with each unit consisting of one share of Series A convertible preferred stock and a five-year warrant to purchase one share of common stock with and exercise price of $1.15 per share. The convertible preferred stock issued in this transaction includes a beneficial ownership limitation on conversion, but has no dividend rights (except to the extent that dividends are also paid on the common stock). The conversion price of the Series A convertible preferred stock in the offering as well as the exercise price of the warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features.

Salarius' Strategy and Ongoing Programs

Salarius' goal is to develop cancer treatments with SP-2577 while attempting to maximize return for investors. To achieve this goal, Salarius is pursuing the following key strategies:

Development of SP-2577 in Ewing Sarcoma Patients

Due to Ewing sarcoma being a rare pediatric cancer with a lack of treatment options, the U.S. Food and Drug Administration ("FDA") has put in place several different types of incentives for companies pursuing therapeutic opportunities for this type of cancer. Salarius has benefited from several of these incentives, including SP-2577's orphan status designation and 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 Salarius will be able to do so. If received, Salarius would have the ability to sell the PRV to other qualifying pharmaceutical companies. Additionally, in December 2019 Salarius 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. Salarius initiated a Phase 1/2 clinical trial in the third quarter of 2018 and is currently in the dose escalation phase. Additional clinical trials will be necessary to receive FDA approval.

Disease background: Ewing sarcoma is a devastating pediatric and young adult cancer that suffers from a lack of 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. Based on data from the National Institute of Health ("NIH") and physician collaborators, Salarius believes 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 Salarius aims to help.

Expand SP-2577 Market by Pursuing Large Market Indications

In parallel to Salarius' development of SP-2577 in Ewing sarcoma patients, Salarius is conducting a Phase 1/2 clinical trial in Advanced Solid Tumors, including patients with breast, ovarian and prostate cancers, as well as patients with sarcomas. LSD1 has been implicated in several advanced solid malignancies, with high levels of LSD1 expression often associated with more aggressive cancers. The possible markets for successful therapies in these indications could be large and thus greatly expand the potential opportunities for SP-2577 outside of Ewing

sarcoma. In December 2018, Salarius received FDA agreement to the protocol design for a second Phase 1/2 trial for SP-2577, an Advanced Solid Tumor study. The trial opened in the second quarter of 2019 and is currently in the dose escalation phase. This trial will study single agent SP-2577 in advanced malignancies, excluding Ewing sarcoma and central nervous system tumors.

The following table lists Salarius' programs and their respective stages of development:

Product Candidate	Target	Disease Area	Development Stage	Sponsor
Clinical				
SP-2577	LSD1	Ewing sarcoma	Phase 1/2, active	Salarius
SP-2577	LSD1	Advanced Solid	Phase 1/2, active	Salarius

LSD1 Overview

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 malignances. 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.

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.

Salarius believes that SP-2577 is different from the majority of LSD1 inhibitors currently in clinical development because in addition to inhibiting LSD1's enzymatic activity, it also more comprehensively inhibits LSD1's scaffolding properties. Salarius also believes that SP-2577 is one of two reversible LSD1 inhibitors in clinical development and that there are three other LSD1 inhibitors in clinical development are all irreversible. Some irreversible inhibitors have struggled in clinic because, in addition to playing a role in carcinogenesis, LSD1 is involved in regulating genes in normal, healthy cells. Hence, irreversible inhibition of LSD1 may result in unwanted, on-target toxicities, limiting dosing for irreversible LSD1 inhibitors. Based on internal and published data, SP-2577 and its closely related predecessor compound (SP-2509) have been observed to reversibly bind to LSD1, which Salarius hypothesizes may avoid these unwanted toxicities and allow more flexible dosing strategies by potentially having a wider therapeutic window. This potential is being studied and developed in Salarius' ongoing clinical program.

Phase 1/2 Clinical Trials

Ewing Sarcoma

Salarius is conducting a multi-site, open-label Phase 1/2 trial of SP-2577 for treatment of relapsed/refractory Ewing sarcoma patients. The clinical trial consists of a dose escalation to determine the maximum tolerated dose, followed by a dose expansion phase and can enroll up to 50 patients. 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.

Salarius initiated this trial in the third quarter of 2018. As of December 31, 2019, several patients have been treated at various dose levels, the highest being dose level 5. Dose escalation levels are shown in the table below.

Dose Level	Twice Daily Dose (mgs)	Percent increase from preceding dose level	Total Daily Dose (mgs)
1	75	0	150
2	150	100%	300
3	300	100%	600
4	600	100%	1200
5	900	50%	1800
6	1200	33%	2400
7	1500	25%	3000

Salarius has eight active sites: Children's Hospital Los Angeles, Moffit Cancer Center, Dana-Farber Cancer Institute, MD Anderson Cancer Center, Johns Hopkins All Children's Hospital, Nationwide Children's Hospital, Memorial Sloan Kettering and the Sarcoma Oncology Center.

Advanced Solid Tumors

Salarius' second company-sponsored trial is in Advanced Solid Tumors. It is an open-label Phase 1/2 trial of SP-2577 in patients with advanced cancers, excluding Ewing sarcoma. The clinical trial follows a similar format to the Ewing sarcoma trial. It will consist of a dose escalation and dose expansion phase and can enroll up to 50 patients. Patients must be diagnosed with advanced or recurrent, histologically or cytologically confirmed, solid malignancy that is either metastatic or unresectable.

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 MTD and assessment of preliminary signs of anti-tumor activity. Additionally, the trial will look at exploratory markers including Hemoglobin F to assess disease burden, drug effect, and tumor response.

Ongoing Development Programs

In addition to the aforementioned clinical trials, Salarius is exploring other opportunities with SP-2577 which include, in combination with immunotherapy agents (checkpoint inhibitors), patients with select tumor mutations, and in hematological malignancies.

Recent preclinical studies demonstrated that LSD1 inhibition has the potential to sensitize refractory patients to checkpoint inhibitors. While checkpoint inhibitors have been successful in a subset of patients, they remain ineffective in a large portion of cancer patients. Considering that the checkpoint inhibitor market is already a multibillion-dollar market, drugs that can be used to increase the clinical benefit of checkpoint inhibitors are attractive. Importantly, recent data shows that certain mutations in chromatin modifying complexes (e.g. mutations in the SWI/SNF complex) could increase tumor sensitivity to LSD1's immunomodulatory effects. Salarius is currently assessing the potential of Seclidemstat to be combined with checkpoint inhibitors through ongoing and planned studies.

Cancer patients who harbor select tumor mutations (e.g., UTX, TET2) may be more susceptible to LSD1 inhibition. As such, identifying patients with these types of mutations could allow Salarius to enrich for patients that have an increased chance of benefiting from SP-2577 treatment. Salarius is currently conducting preclinical work to identify mutations that may increase patient response to SP-2577's therapeutic effects.

Strategic Collaborations and License Agreements

The University of Utah Research Foundation

On August 3, 2011, Salarius 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, Salarius 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, Salarius 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 Salarius ceases to carry on its 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, Salarius may terminate the agreement at any time upon ninety days' notice to the University of Utah.

HLB Life Sciences - South Korea

On November 25, 2016, Salarius entered into an Exclusive Pharmaceutical Sublicense Agreement with HLB Life Sciences ("HLBLS"), a South Korean company, under which HLBLS sublicensed from Salarius the patent and technology rights related to SP-2577 mesylate salt in South Korea, and for the right to develop, produce, manufacture, use and sell the drug in South Korea. Each of Salarius and HLBLS have agreed to report to the other party any intellectual or tangible property improvements or enhancements, along with a written description and sample, and have granted the other party a license to use such improvements or enhancements.

Salarius received from HLBLS a signing milestone payment not exceeding $500,000 upon entering into the agreement and may receive future annual net royalties ranging from 5% to 20% of net sales by HLBLS based on the amount of net sales in a particular year and whether the product is covered by a valid claim of Salarius' patent or utilizes Salarius' know-how, together with a percentage of any sublicense income between 25% to 35%. The agreement will continue until there are no remaining royalty payment obligations, which is expected to be between 2030 and 2034.

Either party may terminate the agreement upon the other party's breach under the agreement following a one hundred twenty-day cure period. In addition, Salarius may terminate the agreement upon notice if HLBLS ceases to use commercially diligent efforts for the first commercial sale of a licensed product, or if HLBLS fails to pay any amounts due under the agreement upon thirty days' notice. In the event Salarius' agreement with the University of Utah is terminated, HLBLS and Salarius have agreed to use their best efforts to execute a license agreement between the University of Utah and HLBLS to continue the royalty arrangements contained in the agreement.

Cancer Prevention and Research Institute of Texas

On June 1, 2016, Salarius entered into a Cancer Research Grant Contract with Cancer Prevention and Research Institute of Texas ("CPRIT"), under which CPRIT agreed to provide up to $18.7 million in funds for product development activities set forth within the scope of the contract. Under the agreement, Salarius must provide matching funds equal to 50% of the funds provided by CPRIT. Salarius must make a good faith effort to spend at least 50% of the CPRIT and matching funds within the State of Texas with Texas-based employees or contractors. This is a 3-year award originally expired on May 31, 2019. A six-month extension was approved by CPRIT in May 2019 and an additional six-month extension through May 2020. The grant now expires on May 31, 2020 with extension available.

Upon commercialization of SP-2577, and if Salarius' revenue is above a specified dollar threshold, Salarius is required to pay a single digit percentage 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 Salarius during the revenue term, Salarius will continue to pay CPRIT a reduced revenue sharing percentage during the remainder of the revenue term. Additionally, if Salarius is 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 Salarius at its discretion. CPRIT may also terminate the agreement upon an event of default, which includes Salarius' failure to conduct the project within the scope agreed by the parties, Salarius' material breach of the agreement, Salarius' failure to comply with applicable law, or bankruptcy or discontinuation of Salarius' 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 Salarius terminates the agreement, CPRIT may require Salarius to repay some or all of the disbursed grant.

Manufacturing

Salarius does not own or operate manufacturing facilities for the production of SP-2577 or other product candidates that Salarius develops, nor does it have plans to develop its own manufacturing operations in the foreseeable future. Salarius currently depends on third-party contract manufacturers for all its required raw materials, active pharmaceutical ingredients, and finished product candidates for its clinical trials. Salarius currently employs internal resources and third-party consultants to manage Salarius' manufacturing contractors.

Sales and Marketing

Salarius has not yet defined its sales, marketing or product distribution strategy for SP-2577 or any of Salarius' other product candidates because its product candidates are still in pre-clinical or early-stage clinical development. Salarius' commercial strategy may include the use of strategic partners, distributors, a contract sale force, or the establishment of its own commercial and specialty sales force. Salarius plans to further evaluate these alternatives when and if it approaches FDA approval for one of its product candidates.

Intellectual Property

As of December 31, 2019, Salarius had a portfolio of 37 patents and patent applications of which 25 were issued or allowed and 12 are pending applications. This portfolio includes composition of matter and methods of use patents on Salarius' lead candidate, SP-2577. These patents and patent applications are owned by the University of Utah Research Foundation and are exclusively licensed to Salarius.

In the United States, Salarius' anticipated first target market, Salarius has 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.

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

LSD1 Inhibition

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 five LSD1 inhibitors being tested in clinic which are shown in the table below. The listed LSD1 inhibitors are in Phase 1 or 2 trials for a variety of cancer types.

Company	Binding Mechanism	Drug Name	Latest Phase
Salarius	Reversible	SP-2577	Phase 1/2
Incyte	Irreversible	INCB59872	Phase 1/2
Oryzon	Irreversible	ORY-1001 (RG6016)	Phase 2
Celgene	Reversible	CC-90011	Phase 1
Imago	Irreversible	IMG-7289	Phase 2

Competitive Differentiations

Salarius believes 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, which make up most of the competitions' drugs, Salarius' 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 recently 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 Salarius hypothesizes may grant it therapeutic advantages over the competition. To further justify this hypothesis, Salarius compared the ability of SP-2577 and an irreversible LSD1 inhibitor, specifically GSK-LSD1 (analogue to GSK's former clinical candidate), to affect cancer cell growth in vitro. SP-2577 was able to inhibit cell growth across 32 cancer cell types compared to GSK-LSD1.

Government Regulation

FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable United States requirements at any time during the product development process may subject a company to a variety of administrative or judicial sanctions, such as imposition of clinical hold, FDA refusal to approve pending NDAs, warning or untitled letters, withdrawal of approval, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Salarius cannot market a drug product candidate in the United States until the drug has received FDA approval. The steps 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;
- 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 to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a New Drug Approval ("NDA") after completion of all pivotal clinical trials;

- satisfactory completion of an FDA advisory committee review, if applicable;
- 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.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

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 or GMP. 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.

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, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. 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 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. In most cases the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted 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. 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. Under the Prescription Drug User Fee Act, ("PDUFA"), guidelines 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.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also 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 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 review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. 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 cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

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 testing, or information, in order for the FDA to reconsider the application. If, or when, 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 risk evaluation and mitigation strategy ("REMS") to ensure that the benefits of the drug outweigh the potential risks. A REMS can include a medication guide, a communication plan for healthcare professionals and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry and other measures that the FDA deems necessary to assure the safe use of the drug. 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 or 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.

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 very 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.

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. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or there is a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. 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. Salarius has 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, Salarius expects 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. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis

of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug product subject to accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In addition, under the provisions of 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 must 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 FDA will either grant or deny the request.

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 by allowing for approval based on a surrogate endpoint likely to predict clinical benefit of the underlying drug, rather than through a direct measure of clinical benefit. Even if Salarius receives one of these 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 Salarius with a material commercial advantage.

Post-Approval Requirements

Once an NDA is approved, a product may be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

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 cGMPs 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 cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. 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, warning letters or 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, Salarius 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 Salarius' products. Whether or not Salarius obtains FDA approval for a product, Salarius would need to obtain the necessary approvals by the comparable foreign regulatory authorities before Salarius 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 each country's national health authority and an independent ethics committee, 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, Salarius 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.

In Canada, biopharmaceutical product candidates are regulated by the Food and Drugs Act and the rules and regulations promulgated thereunder, which are enforced by the Therapeutic Products Directorate of Health Canada ("TPD"). Before commencing clinical trials in Canada, an applicant must complete pre-clinical studies and file a CTA with the TPD. After filing a CTA, the applicant must receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. To obtain regulatory approval to commercialize a new drug in Canada, a new drug submission ("NDS"), must be filed with the TPD. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities' rules, regulations and guidelines and demonstrates favorable safety and efficacy and receives a favorable risk/benefit analysis, the TPD issues a notice of compliance which allows the applicant to market the product.

Other Healthcare Laws

Although Salarius currently does not have any products on the market, Salarius' 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 Salarius conducts its 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 Salarius' 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 that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, 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 interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare

covered business, the Anti-Kickback Statute has been violated. In addition, 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. Violations of this law are punishable by up to five 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, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. 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. In addition, Salarius' future activities relating to the reporting of wholesaler or estimated retail prices for Salarius' products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for Salarius' products, and the sale and marketing of Salarius' products, are subject to scrutiny under this law. 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 $5,500 and $11,000 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 Health Insurance Portability and Accountability Act ("HIPAA") created new federal criminal statutes that prohibit among other actions, 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.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that any of Salarius' products are sold in a foreign country, Salarius may be subject to similar foreign laws.

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 independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a 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. 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 ACA imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members.

Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Because Salarius intends to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, Salarius intends to develop a comprehensive compliance program that establishes internal control to facilitate adherence to the rules and program requirements to which Salarius 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 Salarius' operations are found to be in violation of any of such laws or any other governmental regulations that apply to Salarius, Salarius 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 Salarius' operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect Salarius' ability to operate its business and its 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 Salarius' 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 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. 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. Substantial new provisions affecting compliance have also been enacted, which may require Salarius to modify Salarius' business practices with healthcare providers and entities, and a significant number of provisions are not yet, or have only recently become, effective.

In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of its product candidate.

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 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 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to 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, 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.

Coverage and Reimbursement

Sales of Salarius' product candidates, once approved, will depend, in part, on the extent to which the costs of Salarius' 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 its products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of its products. Sales of Salarius' product candidates, and any future product candidates, will therefore depend substantially on the extent to which the costs of Salarius' product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for Salarius' 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 Salarius to provide scientific and clinical support for the use of Salarius' 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 Salarius' net revenue and results. If these third-party payors do not consider Salarius' products to be cost-effective compared to other therapies, they may not cover Salarius' products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow Salarius to sell its products on a profitable basis. Decreases in third-party reimbursement for Salarius' products once approved or a decision by a third-party payor to not cover its products could reduce or eliminate utilization of Salarius' products and have an adverse effect on its 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 Salarius' products once approved or additional pricing pressures.

Facilities

Salarius' principal executive offices are located in the Johnson & Johnson, JLABS facility, located at the Texas Medical Center in Houston, Texas, under a month-to-month lease. This facility consists of approximately 500 square feet and accommodates Salarius' general and administrative activities. Salarius does not own any real property. Salarius believes that its leased facility is adequate to meet its current needs and that additional facilities will be available on commercially reasonable terms to meet future needs.

Employees

As of December 31, 2019, Salarius had seven full-time employees and one part-time employee. Salarius has never had a work stoppage, and none of its employees is represented by a labor organization or under any collective bargaining arrangements. Salarius considers its employee relations to be good.

Legal Proceedings

Salarius is not currently a party to any legal proceedings the outcome of which Salarius believes, if determined adversely to Salarius, would individually or in the aggregate, have a material adverse effect on its business, financial condition, or results of operations. From time to time, Salarius 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, our wholly owned subsidiary, Falcon Acquisition Sub, LLC, merged with and into Salarius Pharmaceuticals, LLC ("Private Salarius"), with Private Salarius becoming our wholly owned subsidiary (the "Merger"), and we changed our named to Salarius Pharmaceuticals, Inc. Our principal executive offices are located at 2450 Holcombe Blvd., Suite J-608, Houston, TX 77021, and our telephone number is (346) 772-0346. 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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed under the heading "Risk Factors" of this report, and elsewhere in this annual report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Salarius' financial statements and related notes. The risks and uncertainties described below may not be the only ones faced by Salarius. If any of the risks actually occur, Salarius' business, financial condition, operating results and prospects could be materially and adversely affected. These forward-looking statements speak only as of the date hereof. Salarius expressly disclaims any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in Salarius' expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Risks Related to the Development of Salarius' Product Candidates

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 its 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 its 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 its business. If we are not successful in developing an approved product using its 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 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 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 in recruiting qualified patients in its clinical trials;
- failure by clinical sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by Salarius clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical trials;
- 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 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; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of its product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for its 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.

Salarius’ 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.

Salarius has concentrated its research and development efforts to date on a limited number of product candidates based on its epigenetic enzyme therapeutic platform and identifying its initial targeted disease indications. Salarius' future success depends on its successful development of viable product candidates. Currently, only one of its product candidates Seclidemstat, a reversible LSD1 inhibitor, is in Phase 1 clinical development, and the remainder of its product candidates are in pre-clinical development. There can be no assurance that Salarius will not experience problems or delays in developing its 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 Salarius' product candidates in either the United States or the European Union or how long it will take to commercialize its 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 Salarius' ability to generate sufficient product revenue, and Salarius' business, financial condition, results of operations and prospects may be harmed.

Salarius' 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 its product candidates could cause Salarius 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.

In addition, to date Salarius' product candidates have been studied in only a very limited number of patients. Salarius may experience a high rates or severity of adverse events and comparable or high rates of discontinuation in testing in its future clinical trials. There is no guarantee that severe side effects will not be identified through ongoing clinical trials of Salarius' 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 Salarius' product candidates for their proposed indications. Specifically, as a result of concerns regarding the potential teratogenic and abortifacient effects of SP-2577, pregnant women were excluded from the conducted studies.

Additionally, even if one or more of its product candidates receives marketing approval, and Salarius or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- Salarius 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;
- Salarius could be sued and held liable for harm caused to patients; and
- its reputation may suffer.

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

Salarius' product development program may not uncover all possible adverse events that patients who take its product candidates may experience. The number of subjects exposed to Seclidemstat or its other

product candidates and the average exposure time in the clinical development program may be inadequate to detect rare adverse events, or chance findings, that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature use a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, Salarius cannot be fully assured that rare and severe side effects of Seclidemstat or its other product candidates will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to the drug. If such safety problems occur or are identified after Seclidemstat or another product candidate reaches the market, the FDA may require that Salarius amend the labeling of the product or recall the product, or may even withdraw approval for the product.

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

Salarius currently has one product candidate in Phase 1/2 clinical trials for advanced solid tumors - Seclidemstat. This is only one of the multiple indications for which Salarius plans to develop this product candidate. There can be no assurance that the data that Salarius develops for its product candidates in its planned indications will be sufficient to obtain regulatory approval.

In addition, none of its product candidates have advanced into a pivotal clinical trial for Salarius' proposed indications and it may be years before any such clinical trial is initiated and completed, if at all. Salarius is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and Salarius may never receive such regulatory approval for any of its product candidates. Salarius cannot be certain that any of its product candidates will be successful in clinical trials or receive regulatory approval. Further, its product candidates may not receive regulatory approval even if they are successful in clinical trials. If Salarius does not receive regulatory approvals for its product candidates, Salarius may not be able to continue its 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 Salarius' 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. Salarius' 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. Salarius will have to conduct larger, well-controlled trials in its 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. Salarius does not know whether any Phase 1, Phase 2, Phase 3, or other clinical trials Salarius 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 its drug candidates.

Salarius may use its 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 Salarius has limited financial and human resources, it 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. Salarius' resource allocation decisions may cause it to fail to capitalize on viable commercial products or more profitable market opportunities. Salarius' spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. Salarius may also enter into additional strategic collaboration agreements to develop and commercialize some of its programs and potential product candidates in indications with potentially large commercial markets. If Salarius does not accurately

evaluate the commercial potential or target market for a particular product candidate, it 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 Salarius to retain sole development and commercialization rights to such product candidate, or Salarius 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.

Salarius may find it difficult to enroll patients in its clinical trials given the limited number of patients who have the diseases for which its 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 Salarius' product candidates is essential to its success. The timing of Salarius' clinical trials depends in part on the rate at which Salarius can recruit patients to participate in clinical trials of its product candidates, and Salarius may experience delays in its clinical trials if Salarius encounters difficulties in enrollment, clinical enrollment is inherently difficult, and often time consuming.

The eligibility criteria of Salarius' planned clinical trials may further limit the available eligible trial participants as Salarius expects to require that patients have specific characteristics that Salarius can measure or meet the criteria to assure their conditions are appropriate for inclusion in its clinical trials. Salarius may not be able to identify, recruit, and enroll a sufficient number of patients to complete its 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 its planned clinical trials. If patients are unwilling to participate in Salarius' clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of its product candidates may be delayed.

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

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

The use or misuse of Salarius' product candidates in clinical trials and the sale of any products for which Salarius may obtain marketing approval exposes Salarius to the risk of potential product liability claims. Product liability claims might be brought against Salarius by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with its product candidates and approved products, if any. There is a risk that Salarius' product candidates may induce adverse events. If Salarius cannot successfully defend against product liability claims, it could incur substantial liability and costs. Patients with the diseases targeted by Salarius' 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 Salarius' product candidates. Such events could subject Salarius to costly litigation, require it to pay substantial amounts of money to injured patients, delay, negatively impact or end its opportunity to receive or maintain regulatory approval to market its products, or require Salarius to suspend or abandon its commercialization efforts. Even in a circumstance in which an adverse event is unrelated to Salarius' product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay Salarius' regulatory approval process or impact and limit the type of regulatory approvals its 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 Salarius' business, financial condition or results of operations.

Although Salarius has product liability insurance, which covers its clinical trials in the United States, for up to $2.0 million per occurrence, up to an aggregate limit of $5.0 million, its insurance may be insufficient to reimburse it for any expenses or losses Salarius may suffer. Salarius will also likely be required to increase its product liability insurance coverage for the advanced clinical trials that it plans to initiate. If Salarius obtains marketing approval for any of its product candidates, it will need to expand its insurance coverage to include the sale of commercial products. There is no way to know if Salarius will be able to continue to obtain product liability coverage and obtain expanded coverage if it requires it, in sufficient amounts to protect it against losses due to liability, on acceptable terms, or at all. Salarius may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, its insurance coverage. Where Salarius has provided indemnities in favor of third parties under its agreements with them, 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 Salarius alleging that one of its 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 Salarius, 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, its 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 Salarius' product liability insurance, which Salarius would then be required to pay itself;
- an increase in Salarius' 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 Salarius' business; and
- damage to Salarius' reputation and the reputation of its products and its technology.

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

Risks Related to Salarius' Financial Condition and Capital Requirements

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.

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. As of February 29, 2020, 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 $6,936,263 and $1,669,637 for each of the years ended December 31, 2019 and 2018. 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 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. The amount and timing of our future funding requirements will depend on many factors, including 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 develop our product candidates.

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 its 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.

Salarius has never generated any revenue from product sales and may never generate revenue or be profitable.

Salarius has no products approved for commercialization and has never generated any revenue. Salarius' ability to generate revenue and achieve profitability depends on its 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 its product candidates. Salarius does not anticipate generating revenue from product

sales for the foreseeable future. Salarius' ability to generate future revenue from product sales depends heavily on its success in many areas, including but not limited to:

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

Even if one or more of the product candidates that Salarius develops is approved for commercial sale, Salarius anticipates incurring significant costs associated with commercializing any approved product candidate. Portions of its 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. Salarius will also have to develop, contract for or acquire manufacturing capabilities to continue development and potential commercialization of its product candidates. Salarius will need to develop or procure its drug product in a commercially feasible manner in order to successfully commercialize any future approved product; if any. Additionally, if Salarius is not able to generate revenue from the sale of any approved products, Salarius may never become profitable.

Raising additional capital may cause dilution to Salarius' stockholders, restrict its operations or require Salarius to relinquish rights.

Salarius completed an $11.0 million capital raise on February 11, 2020. This raise caused significant dilution to stockholders who owned Salarius shares prior to this capital raise. To the extent that Salarius raises additional capital through the sale of equity, convertible debt or other securities convertible into equity the ownership interest of Salarius' stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of Salarius' equity holders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting Salarius' ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If Salarius raises additional funds through strategic collaborations or licensing arrangements with third parties, Salarius may have to relinquish valuable rights to its product candidates or future revenue streams or grant licenses on terms that are not favorable to Salarius. Salarius cannot be assured that it will be able to obtain additional funding when necessary to fund its entire portfolio of product candidates to meet its projected plans. If Salarius is unable to obtain funding on a timely basis, Salarius may be required to delay or discontinue one or more of its development programs or the commercialization of any product candidates or be unable to expand its operations or otherwise capitalize on potential business opportunities, which could materially harm Salarius' business, financial condition, and results of operations.

Salarius has 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 Salarius may receive may be, subject to the risks and contingencies set forth below under the risk factor titled "Reliance on government funding for Salarius' programs may add uncertainty to its research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit its ability to take specified actions, increase the costs of commercialization and production of product candidates developed under

those programs and subject it to potential financial penalties, which could materially and adversely affect its business, financial condition and results of operations." Although Salarius might apply for government contracts and grants in the future, it cannot assure you that it 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 Salarius' business.

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

Salarius may seek breakthrough therapy designation by the FDA for one or more of its product candidates, but it might not receive such designation.

Salarius may seek a breakthrough therapy designation from the FDA for some of its 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 Salarius believes one of its product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation.

A potential breakthrough therapy designation by the FDA for Salarius' product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that Salarius' product candidates will receive marketing approval.

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 Salarius' 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.

Salarius received Fast Track designation for one or more of its product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process.

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. Salarius recently received Fast Track designation for a product candidate. However, Fast Track designation does not ensure that Salarius will receive marketing approval or that approval will be granted within any particular time frame. Salarius 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 Salarius' clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Even if Salarius obtains regulatory approval for a product, Salarius will remain subject to ongoing regulatory requirements.

If any of Salarius' product candidates are approved, Salarius 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, Salarius and its 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 Salarius receives for its 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. Salarius 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 its original marketing approval for a product candidate was obtained through an accelerated approval pathway, Salarius could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for its 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 Salarius, including requiring withdrawal of the product from the market. If Salarius fails to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of Salarius' ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by Salarius;
- impose restrictions on Salarius' operations, including closing its contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require Salarius 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 its ability to develop and commercialize its products and the value of Salarius and its operating results would be adversely affected.

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

In the United States, there have been and continue to be a number of legislative 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 Patient Protection and Affordable Care Act ("ACA"), as amended by the Health Care and Education Reconciliation Act (the "Health Care Reform Law"), was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Health Care Reform Law, 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, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted and Salarius expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for its product candidates, or additional pricing pressures.

Salarius 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 Salarius is unable to comply, or has not fully complied, with such laws, it could face substantial penalties.

If Salarius obtains FDA approval for any of its product candidates and begins commercializing those products in the United States, its 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 physician sunshine laws and regulations. These laws may impact, among other things, its proposed sales, marketing, and education programs. In addition, Salarius may be subject to patient privacy regulation by both the federal government and the states in which Salarius conduct its business. The laws that may affect its ability to operate 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 and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- 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 federal physician sunshine requirements under the Health Care Reform Laws requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; 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, 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 effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of Salarius' business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If Salarius' operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to Salarius, Salarius may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate Salarius' business and its results of operations.

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

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

In addition to the funding Salarius has received to date, it intends 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 Salarius violates 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 Salarius may receive could also impose requirements to make payments based upon sales of its products, if any, in the future.

Salarius may not have the right to prohibit the U.S. government from using specified technologies developed by it, and Salarius may not be able to prohibit third-party companies, including its 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 Salarius licenses now or in the future.

In addition, government contracts and grants normally contain additional requirements that may increase Salarius' costs of doing business, reduce its profits, and expose it 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 Salarius' research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If Salarius fails to maintain compliance with any such requirements that may apply to it now or in the future, Salarius may be subject to potential liability and to termination of Salarius' contracts.

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

Salarius' research and development activities and its third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of its product candidates and other hazardous compounds. Salarius and its 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 Salarius' and its manufacturers' facilities pending their use and disposal. Salarius cannot eliminate the risk of contamination, which could cause an interruption of its 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 Salarius believes that the safety procedures utilized by it and its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, Salarius cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Salarius may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail Salarius' use of specified materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. Salarius cannot predict the impact of such changes and cannot be certain of its future compliance. Salarius does not currently carry biological or hazardous waste insurance coverage.

Risks Related to Salarius' Intellectual Property

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

Presently, Salarius has rights to the intellectual property, through licenses from third parties and under patents and patent applications that Salarius owns, to modulate only a subset of the known epigenetic enzyme targets. Because Salarius' programs may involve a range of targets, including targets that require the use of proprietary rights held by third parties, the growth of its business may depend in part on Salarius' ability to acquire, in-license or use these proprietary rights. In addition, Salarius' product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. Salarius 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 it identifies. 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 Salarius may consider attractive. These established companies may have a competitive advantage over Salarius due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, Salarius has previously and may continue to collaborate with academic institutions worldwide to accelerate its 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, Salarius may be unable to negotiate a license within the specified time frame or under terms that are acceptable to it. If Salarius is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking Salarius' ability to pursue its program.

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

Salarius intends to rely on patent rights for its product candidates and any future product candidates. If Salarius is unable to obtain or maintain exclusivity from the combination of these approaches, Salarius may not be able to compete effectively in its markets.

Salarius relies or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to its technologies and product candidates. Its success depends in large part on its and its 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 its proprietary technology and products.

Salarius has sought to protect its proprietary position by filing patent applications in the United States and abroad related to its product candidates that are important to its business. This process is expensive and time consuming, and Salarius 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 Salarius will fail to identify patentable aspects of its 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 Salarius owns or in-licenses may fail to result in issued patents with claims that cover its product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to its 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 Salarius' 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, Salarius' patents and patent applications may not adequately protect its intellectual property, provide exclusivity for its product candidates, or prevent others from designing around Salarius claims. Any of these outcomes could impair Salarius' ability to prevent competition from third parties, which may have an adverse impact on its business.

Salarius, independently or together with its licensors, has filed several patent applications covering various aspects of its product candidates. Salarius 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 Salarius after patent issuance could deprive Salarius of rights necessary for the successful commercialization of any product candidates that Salarius may develop. Further, if Salarius encounters delays in regulatory approvals, the period of time during which Salarius could market a product candidate under patent protection could be reduced.

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

Salarius may not have sufficient patent term protections for its product candidates to effectively protect its 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 its product candidates are obtained, once the patent life has expired for a product candidate, Salarius 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").

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 Salarius' product candidates. Salarius will likely rely on patent term extensions, and Salarius cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, Salarius may not be able to maintain exclusivity for its product candidates for an extended period after regulatory approval, if any, which would negatively impact its business, financial condition, results of operations and prospects. If Salarius does not have sufficient patent terms or regulatory exclusivity to protect its product candidates, its 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 Salarius' ability to protect its products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents.

As is the case with other biotechnology companies, Salarius' 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 Salarius' 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 Salarius' ability to obtain new patents or to enforce Salarius' existing patents and patents that it might obtain in the future. Some of Salarius' 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 Salarius to pursue similar patent claims in patent applications Salarius may prosecute in the future.

Salarius' 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 Salarius' patent portfolio significantly reduces, but may not eliminate, its 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 Salarius' business.

For Salarius' 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 Salarius' business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents, all of which could have a material adverse effect on Salarius' 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. A third party that files a patent application in the USPTO after that date but before Salarius could therefore be awarded a patent covering an invention of Salarius' even if

Salarius had made the invention before it was made by the third party. This will require Salarius to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, Salarius' ability to obtain and maintain valid and enforceable patents depends on whether the differences between its technology and the prior art allow its 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, Salarius cannot be certain that it was the first to either (i) file any patent application related to its product candidates or (ii) invent any of the inventions claimed in its 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 Salarius' 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 Salarius' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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

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

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

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

Salarius' commercial success depends in part on its ability to develop, manufacture, market and sell its product candidates and use its 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. Salarius is aware of U.S. and foreign patents and pending patent applications owned by third parties that cover therapeutic uses of epigenetic inhibitors. Salarius is currently monitoring these patents and patent applications. Salarius 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, Salarius 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 its product candidates or

technologies, Salarius may not be free to manufacture or market its product candidates, as planned, absent such a license, which may not be available to Salarius on commercially reasonable terms, or at all.

It is also possible that Salarius has 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 Salarius, to identify all third-party patent rights that may be relevant to its 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. Salarius 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 its technology. In addition, Salarius 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 Salarius may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by its activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover Salarius' technologies, its product candidates or the use of its 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 Salarius is developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against Salarius may obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize one or more of its 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 its business. In the event of a successful claim of infringement against Salarius, Salarius may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign its infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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

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

Salarius 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 Salarius identifies as necessary for its 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 Salarius may consider attractive. These established companies may have a competitive advantage over Salarius due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive Salarius to be a competitor may be unwilling to assign or license rights to Salarius. Even if Salarius is able to license or acquire third-party intellectual property rights that are necessary for its product candidates, there can be no assurance that they will be available on favorable terms.

Salarius collaborates with academic institutions worldwide to identify product candidates, accelerate its research and conduct development. Typically, these institutions have provided Salarius 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, Salarius may be unable to negotiate a license within the specified

timeframe or under terms that are acceptable to Salarius. If Salarius is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking its ability to pursue a program of interest to Salarius.

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

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

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

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

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

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

Competitors may infringe Salarius' patents or the patents of its licensors. If Salarius or one of its licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of its product candidates, the defendant could counterclaim that the patent covering its 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 Salarius or declared by the USPTO may be necessary to determine the priority of inventions with respect to Salarius' patents or patent applications or those of its licensors. An unfavorable outcome could require Salarius to cease using the related technology or to attempt to license rights to it from the prevailing party. Salarius' business could be harmed if the prevailing party does not offer Salarius a license on commercially reasonable terms. Its defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract its management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on its ability to raise the funds necessary to continue its clinical trials, continue its research programs, license necessary technology from third parties, or enter into development partnerships that would help Salarius bring its 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 Salarius' 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 its common stock.

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

Salarius employs individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including Salarius' competitors or potential competitors. Although Salarius has written agreements and makes every effort to ensure that its employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for Salarius, Salarius may in the future be subject to any claims that its 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 Salarius fails in defending any such claims, in addition to paying monetary damages, Salarius may lose valuable intellectual property rights or personnel, which could adversely impact its business. Even if Salarius is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Salarius may not be able to protect its 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 its 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 Salarius' technologies in jurisdictions where Salarius has not obtained patent protection to develop its own products and may also export infringing products to territories where Salarius has patent protection, but enforcement is not as strong as that in the United States. These products may compete with its products and its 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 Salarius to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce Salarius' patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert Salarius' efforts and attention from other aspects of its business, could put Salarius' patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing and could provoke third parties to assert claims against Salarius. Salarius may not prevail in any lawsuits that Salarius initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, its efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that Salarius develops or licenses.

Risks Related to Salarius' Reliance on Third Parties

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

Salarius has relied upon and plans to continue to rely upon third-parties such as CROs, hospitals, etc. to conduct, monitor and manage its ongoing clinical programs. Salarius relies on these parties for execution of clinical trials and manages and controls only some aspects of their activities. Salarius remains responsible for ensuring that each of its trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and its reliance on these third parties does not relieve Salarius of its regulatory responsibilities. Salarius and its 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 its product candidates in clinical development. If Salarius or any of its CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Salarius to perform additional clinical trials before approving its marketing applications. Salarius cannot be assured that its 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 its clinical trials, comply with

applicable requirements. Its failure to comply with these laws, regulations and guidelines may require Salarius to repeat clinical trials, which would be costly and delay the regulatory approval process.

If any of Salarius' relationships with these third-parties terminate, Salarius 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 Salarius' 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 its clinical trials. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, Salarius' clinical trials may be delayed or terminated and Salarius may not be able to meet its current plans with respect to its product candidates. CROs, in particular, may also involve higher costs than anticipated, which could negatively affect Salarius' financial condition and operations.

In addition, Salarius does not currently have, nor does Salarius currently plan to establish the capability to manufacture product candidates for use in the conduct of its clinical trials, and Salarius lacks the resources and the capability to manufacture any of its product candidates on a clinical or commercial scale without the use of third-party manufacturers. Salarius plans to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce its product candidates for its clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that Salarius expects to use to manufacture its product candidates, and Salarius may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of its product candidates for its clinical trials, and, if approved, ultimately for commercial sale. Although Salarius generally does not expect to begin a clinical trial unless Salarius believes it has 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 its clinical trials and potential timing for regulatory approval of its product candidates, which would harm its business and results of operations.

Salarius expects to rely on third parties to manufacture its clinical product supplies, and Salarius intends to rely on third parties to produce and process its product candidates, if approved, and Salarius' commercialization of any of its product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to provide Salarius with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

Salarius does not currently have nor does it currently plan to develop the infrastructure or capability internally to manufacture its clinical supplies for use in the conduct of Salarius' clinical trials, and Salarius lacks the resources and the capability to manufacture any of its product candidates on a clinical or commercial scale. Salarius currently relies on outside vendors to manufacture its clinical supplies of its product candidates and plans to continue relying on third parties to manufacture its product candidates on a commercial scale, if approved.

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

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

- Salarius may be unable to identify manufacturers on acceptable terms or at all;
- Salarius' third-party manufacturers might be unable to timely formulate and manufacture Salarius' product or produce the quantity and quality required to meet Salarius' clinical and commercial needs, if any;
- contract manufacturers may not be able to execute Salarius' manufacturing procedures appropriately;
- Salarius' future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply its clinical trials or to successfully produce, store and distribute its 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. Salarius does not have control over third-party manufacturers' compliance with these regulations and standards;

- Salarius may not own, or may have to share, the intellectual property rights to any improvements made by Salarius' third-party manufacturers in the manufacturing process for its product candidates; and
- Salarius' third-party manufacturers could breach or terminate their agreement with Salarius.

Each of these risks could delay Salarius' clinical trials, the approval, if any of its product candidates by the FDA or the commercialization of its product candidates or result in higher costs or deprive Salarius of potential product revenue. In addition, Salarius relies on third parties to perform release testing on its 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. Furthermore, if contaminants are discovered in Salarius' supply of its 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. Salarius cannot be assured that any stability or other issues relating to the manufacture of its product candidates will not occur in the future. Additionally, Salarius' manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If Salarius' manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, Salarius' ability to provide its 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 Salarius to commence new clinical trials at additional expense or terminate clinical trials completely.

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

Salarius has entered into strategic collaborations and license agreements with the University of Utah, HLBLS, and CPRIT. While Salarius may seek to enter into future collaborations for the development and commercialization of its product candidates, there can be no assurance that it will be able to do so. Even if Salarius is 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 Salarius may be unable to realize in full or in part the potential benefits of any of its 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 Salarius' share of potential future profits from the associated program, and may require it to relinquish potentially valuable rights to its current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to Salarius;
- collaborators may cease to devote resources to the development or commercialization of Salarius' product candidates if the collaborators view its 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 Salarius to litigation and potential liability;
- the collaborations may not result in Salarius achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for Salarius 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 Salarius' product candidates.

Salarius enters into various contracts in the normal course of its business in which Salarius indemnifies the other party to the contract. In the event Salarius has to perform under these indemnification provisions, it could have a material adverse effect on its business, financial condition and results of operations.

In the normal course of business, Salarius periodically enters into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to Salarius' academic and other research agreements, Salarius typically indemnifies the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which Salarius has secured licenses, and from claims arising from Salarius' or its sublicensees' exercise of rights under the agreement. With respect to Salarius' collaboration agreements, Salarius indemnifies its collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, Salarius indemnifies them from claims arising from the good faith performance of their services.

Should Salarius' obligation under an indemnification provision exceed applicable insurance coverage or if Salarius were denied insurance coverage, Salarius' business, financial condition and results of operations could be adversely affected. Similarly, if Salarius is relying on a collaborator to indemnify Salarius and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify Salarius, its business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Salarius' Product Candidates

Salarius currently has very limited marketing and sales experience. If Salarius is unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell its product candidates, Salarius may be unable to generate any revenue.

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

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

Salarius may attempt to form collaborations in the future with respect to its product candidates, but it may not be able to do so, which may cause it to alter its development and commercialization plans.

Salarius may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to its programs that it believes will complement or augment its existing business. Salarius

may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. Salarius may not be successful in its efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to it, or at all. This may be because Salarius' product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, its 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 its 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 Salarius' product candidates could delay the development or commercialization of its product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, Salarius would need to undertake development and/or commercialization activities at its own expense. If Salarius elects to fund and undertake development and/or commercialization activities on its own, it may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms or at all. If Salarius is unable to do so, it may not be able to develop its product candidates or bring them to market and its business may be materially and adversely affected.

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

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

Salarius faces substantial competition and its competitors may discover, develop or commercialize products faster or more successfully than Salarius.

The development and commercialization of new drug products is highly competitive. Salarius faces 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 it 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 Salarius' competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than Salarius, it could result in its competitors establishing a strong market position before Salarius is able to enter the market.

Many of Salarius' competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than it does. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in its 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 Salarius' 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 Salarius' business, financial condition, results of operations and prospects.

The commercial success of any of Salarius' 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 Salarius obtains the necessary approvals from the FDA and comparable foreign regulatory authorities, the commercial success of Salarius' products will depend in part on the health care providers, patients, and third-party payors accepting its product candidates as medically useful, cost-effective, and safe. Any product that Salarius brings to the market may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of any of Salarius' 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 its 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 its products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, Salarius will not be able to generate sufficient revenue to become or remain profitable.

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

Although a substantial amount of Salarius' effort will focus on the continued clinical testing, potential approval, and commercialization of its existing product candidates, the success of Salarius' business is also expected to depend in part upon its ability to identify, license, discover, develop, or commercialize additional product candidates.

Research programs to identify new product candidates require substantial technical, financial, and human resources. Salarius may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Salarius' 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:

- Salarius' research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- Salarius may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- its product candidates may not succeed in pre-clinical or clinical testing;
- its 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 Salarius' product candidates obsolete or less attractive;
- product candidates Salarius develops may be covered by third parties' patents or other exclusive rights;

- the market for a product candidate may change during Salarius' 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, Salarius may be forced to abandon its development efforts for a program or programs, or Salarius may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on its business, financial condition or results of operations and could potentially cause Salarius to cease operations.

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

The pricing, coverage, and reimbursement of Salarius' approved products, if any, must be sufficient to support its 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 Salarius' approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of its 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, Salarius may have to subsidize or provide products for free or Salarius may not be able to successfully commercialize its 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 Salarius' and what reimbursement codes its 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 Salarius believes the increasing emphasis on cost-containment initiatives in Europe, Canada, 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 Salarius is able to charge for its 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 its products. Salarius expects 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 Salarius' products, if any, may be more difficult to achieve even if they receive regulatory approval.

Risks Related to Salarius' Business Operations

Salarius' future success depends in part on its ability to retain its president and chief executive officer and to attract, retain, and motivate other qualified personnel.

Salarius is a small company with a limited number of employees performing multiple tasks each. Salarius is highly dependent on David J. Arthur, its president and chief executive officer, the loss of whose services may adversely impact the achievement of its 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 Salarius' employment at any time, as he is an "at will" employee. Recruiting and retaining other qualified employees, consultants, and advisors for Salarius' business, including scientific and technical personnel, will also be critical to Salarius success. There is currently a shortage of highly qualified personnel in Salarius' industry, which is likely to continue. Additionally, this shortage of highly qualified personnel is particularly acute in the area where Salarius is located. As a result, competition for personnel is intense and the turnover rate can be high. Salarius 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 Salarius' 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 may impede the progress of Salarius' research, development, and commercialization objectives and would negatively impact Salarius' ability to succeed in its product development strategy.

Salarius will need to expand its organization and Salarius may experience difficulties in managing this growth, which could disrupt its operations.

As of December 31, 2019, Salarius had 7 full-time employees and 1 part-time employee. As Salarius' development and commercialization plans and strategies develop, Salarius expects to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Its 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. Salarius may not be able to effectively manage the expansion of its operations, which may result in weaknesses in its infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Salarius' expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If its management is unable to effectively manage its growth, its expenses may increase more than expected, its ability to generate and/or grow revenue could be reduced and Salarius may not be able to implement its business strategy. Salarius' future financial performance and its ability to commercialize product candidates and compete effectively will depend, in part, on its ability to effectively manage any future growth.

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

Salarius' ability to execute its business plan and maintain operations depends on the continued and uninterrupted performance of its 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 Salarius' and its 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 Salarius' reputation, compel Salarius to comply with disparate state and foreign breach notification laws and otherwise subject it 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, Salarius may not be able to address these techniques proactively or implement adequate preventative measures. If its computer systems are compromised, it could be subject to fines, damages, litigation and enforcement actions, and it could lose trade secrets, the occurrence of which could harm its business. Despite precautionary measures to prevent unanticipated problems that could affect its information technology systems, sustained or repeated system failures that interrupt Salarius' ability to generate and maintain data could adversely affect its ability to operate its 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 Salarius' data practices, which could have a material adverse effect on Salarius' business. Complying with these various laws could cause Salarius to incur substantial costs or require it to change its business practices in a manner adverse to its business.

We may face business disruption and related risks resulting from the recent outbreak of the novel coronavirus 2019 (COVID-19) and President Trump's recent invocation of the Defense Production Act, either of which could have a material adverse effect on our business.

Our development programs could be disrupted and materially adversely affected by the recent outbreak of COVID-19. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the International Health Regulations Emergency Committee of the World Health Organization declaring the outbreak of COVID-19 as a "public health emergency of international concern," and the World Health Organization characterizing COVID-19 as a pandemic. While the COVID-19 outbreak may still be in early stages, international stock markets have begun to reflect the uncertainty associated with the potential economic impact of the outbreak and the significant declines in the Dow Industrial Average at the end of February and in March 2020 has been largely attributed to the effects of COVID-19. In response to the events surrounding the COVID-19 pandemic, President Trump invoked the Defense Production Act, codified at 50 U.S.C. §§ 4501 et seq. (the "Defense Production Act"). Pursuant to the, Defense Production Act the federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense. We are still assessing the potential impact COVID-19 and the invocation of the Defense Production Act may have on our ability to effectively conduct our commercialization efforts and development programs and otherwise conduct our business operations as planned, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or from any action taken by the federal government under the Defense Production Act, including downturns in business sentiment generally or in our industry and business in particular.

Risks Related to Our Common Stock

The terms of the Series A Preferred Stock and the warrants could impede our ability to enter into certain transactions or obtain additional financing.

The terms of the Series A Preferred Stock and 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 Series A Preferred Stock and the warrants and the associated transaction documents. In addition, holders of Series A Preferred Stock and 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 Series A Preferred Stock and 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.

If we are unable to maintain listing of our securities on the Nasdaq Capital Market or another reputable stock exchange, it may be more difficult for our stockholders to sell their securities.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

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

For example, if at any time the bid price of our common stock closes at below $1.00 per share for more than 30 consecutive trading days, we may be subject to delisting from the Nasdaq Capital Market. If we receive a delisting notice, we would have 180 calendar days to regain compliance (subject to any additional 180-day compliance period which may be available to us), which would mean having a bid price above the minimum of $1.00 for at least 10 consecutive days in the 180-day period. During this 180-day period, we would anticipate reviewing our options to regain compliance with the minimum bid requirements, including conducting a reverse stock split. To the extent that we are unable to resolve any listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock. On March 16, 2020, the closing price of our common stock was $0.6995 per share.

Item 1B. Unresolved Staff Comments

Not applicable.

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 16, 2020, we had approximately 152 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.

Unregistered Sale of Equity Securities

On December 11, 2019, we entered into an investor relations consulting services agreement. In accordance with the agreement, we agreed to issue 12,376 unregistered shares of our common stock and $10,000 as consideration for the services performed thereunder. The issuance described above is exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof and Regulation D thereunder.

Item 6. Selected Financial Data

Not required.

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. The MD&A is organized as follows:

- Overview - A discussion of our business and overall analysis of financial and other highlights in order to provide context for the remainder of the MD&A.
- Recent Events - A discussion of our recent financing activities.
- Results of Operations - An analysis of our financial results comparing the years ended December 31, 2019 and 2018.
- Liquidity and Capital Resources - An analysis of changes in our audited consolidated balance sheets and cash flows, and discussion of our financial condition and potential sources of liquidity.
- Critical Accounting Policies and Significant Judgments and Estimates - A discussion of critical accounting policies and those that require us to make subjective estimates and judgments.

Overview

We are a clinical-stage biotechnology company focused on developing effective epigenetic-based cancer treatments for indications with high unmet medical need. Our lead epigenetic enzyme technology was licensed from the University of Utah Research Foundation in 2011.

We are focused on epigenetic strategies for cancer treatment. Epigenetics refers to the system that regulates gene expression through conformational changes to the chromatin rather than changes to the DNA sequence itself. Our lead compound, 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 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.

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 15. 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. The Advanced Solid Tumor ("AST") trial is a single agent dose escalation, dose expansion study enrolling patients with advanced malignancies, excluding Ewing sarcoma or central nervous system tumors.

In addition, 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 recent works have sparked interest in combining LSD1 inhibitors with checkpoint inhibitors. We are conducting preclinical work with SP-2577 in this area.

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 $12,076,700 as of December 31, 2019. 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 upon closing of the merger, 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, 2019, we had cash and cash equivalents of $3.7 million, which includes $1.0 million for funds received from CPRIT. These funds are to be used for allowable expenses, primarily research and development expenses. The grant has a mandatory fund matching requirement. The Company believes that as of December 31, 2019, CPRIT fund matching requirements had been fully met. As of December 31, 2019, we have received an aggregate of $9.6 million from the CPRIT grant and there was $9.1 million of funds available for us to draw upon meeting certain requirements.

We believe that our cash and cash equivalents currently on hand are sufficient to fund our anticipated operating and capital requirements through at least 12 months from the date this report is filed, however we will continue to require substantial additional capital to continue our clinical development activities. 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 and commercialization 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 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.

Recent Events

On February 11, 2020, we completed our underwritten public offering of 7,101,307 Class A Units, plus the full exercise of the underwriter's over-allotment option to purchase an additional 1,252,173 shares and 1,246,519 Class B Units at a per unit price of $1.15. Total gross proceeds from the offering were $11.0 million prior to deducting underwriting discounts and commissions and offering expenses. Each Class A Unit consisted of one share of our common stock and a five-year warrant to purchase one share of our common stock at an exercise price of $1.15 (the “Warrants”). Each Class B Unit consisted of one share of Series A convertible preferred stock (the “Series A Preferred Stock”) and a Warrant.

On October 24, 2019, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC (“Aspire Capital”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may offer to Aspire Capital up to an aggregate of $10.9 million of shares of our common stock over a 30-month period. Upon execution of the agreement, we sold to Aspire Capital 210,526 shares of common stock at $4.75 per share for proceeds of $1.0 million, and we issued to Aspire Capital 101,810 shares of our common stock in consideration for entering into the agreement. In December 2019, we issued to Aspire Capital 438,525 shares of common stock for proceeds of approximately $1.6 million. Under the terms of our recent $11.0 million capital raise, the Aspire Capital agreement can be used in very limited circumstances.

As of December 31, 2019, our available cash was approximately $3.7 million.

Results of Operations

The following table sets forth the consolidated results of our operations for the year ended December 31, 2019 compared to the year ended December 31, 2018.

	Year Ended December 31, 2019	Year Ended December 31, 2018	Change $
Grant revenue	$ 3,465,055	$ 1,951,351	$ 1,513,704
Research and development expenses	4,018,951	1,287,621	2,731,330
General and administrative expenses	7,711,181	2,348,361	5,362,820
Change in fair value of warrant liability	1,311,333	—	1,311,333
Interest income (expense), net	15,648	14,994	654
Income from discontinued operations	1,833	—	1,833
Net loss	$ (6,936,263)	$ (1,669,637)	$ (5,266,626)

Grant Revenue

Grant revenue, which was derived solely from the CPRIT grant, was $3,465,055 during the year ended December 31, 2019 compared to $1,951,351 during the year ended December 31, 2018. The increase in revenue from the CPRIT grant was due to an increase in overall expenses which resulted in an increase in the amount of expenses

reimbursable under the grant. Given the nature of the development process, grant revenue will fluctuate depending on the stage of development and the timing of expenses.

As of December 31, 2019, we had $541,701 of deferred revenue, which consisted of payments received from the CPRIT grant. This deferred revenue is expected to be recognized through the first half of 2020.

Research and Development Expenses

Research and development expenses were $4,018,951 during the year ended December 31, 2019 compared to $1,287,621 during the year ended December 31, 2018. This increase of $2,731,330 was principally due to increased chemistry, manufacturing and control expenses related to production of tablets to be used in clinical trials, as well as consulting fees related to clinical trials and a pre-clinical study for our next generation Seclidemstat program. We initiated our Phase 1 clinical trial for Ewing Sarcoma in September 2018 and have since increased the number of patients enrolled and clinical sites. The Phase 1 clinical trial for advanced solid tumor was initiated in the second quarter of 2019.

General and Administrative Expense

General and administrative expenses were $7,711,181 for the year ended December 31, 2019 compared to $2,348,361 for the year ended December 31, 2018. This increase of $5,362,820 was principally due to increased legal and professional service fees. Legal and professional fees increased significantly in the current period mainly due to merger and financing activities. We incurred approximately $760,000 of legal and professional fees related to the merger with Flex Pharma and financing activities. We also incurred a success fee of $1,350,000 upon the closing of the merger transaction with Flex Pharma.

Insurance expenses increased approximately $474,000 mainly due to higher premium on director and officer liability insurance. Payroll expense increased $470,000 which was primarily due to increases in salaries, wages and stock-based compensation expenses for the year ended December 31, 2019.

Change in Fair Value of Warrant Liability

The change in fair value of warrant liability was primarily due to the fluctuation of the price of our common stock which was $15.17 per share on the date of issuance on July 19, 2019 compared to $3.78 per share on December 31, 2019.

Liquidity and Capital Resources

Overview

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 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. 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. Presently, we have sufficient cash and cash equivalents to enable us to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Annual Report on Form 10-K.

As of December 31, 2019, we had $1,381,255 of working capital and our cash and cash equivalents totaled $3,738,900, which were held in bank deposit accounts and money market funds. Our cash and cash equivalents and restricted cash balance decreased during the year ended December 31, 2019, primarily due to our net loss incurred.

Cash Flows

	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash (used in) provided by:		
Operating activities	$ (11,580,096)	$ 4,177,189
Investing activities	5,607,908	—
Financing activities	3,579,307	1,435,255
Net decrease in cash and cash	$ (2,392,881)	$ 5,612,444

Operating Activities

Cash used in operating activities was $11,580,096 for the year ended December 31, 2019, as compared to $4,177,189 of cash provided by operating activities for the year ended December 31, 2018. This increase in cash used in operating activities was primarily due to payments made for legal and professional services related to the merger transaction as well as research activities. Total payments for legal fees, including spending related to the merger, was approximately $1.7 million for the year ended December 31, 2019. Additionally, there was a one-time nonrecurring payment made for liabilities assumed from Flex Pharma of approximately $1.7 million.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2019 was related to $5,403,634 net cash received from Flex Pharma upon the merger and $204,274 net cash received from the sale of the HOTSHOT business.

There were no cash flows from investing activities for the year ended December 31, 2018.

Financing Activities

Net cash provided by financing activities was $3,579,307 and $1,435,255 for the years ended December 31, 2019 and 2018, respectively. Proceeds received from issuances of equity securities increased from $2,025,269 for the year ended December 31, 2018 to $4,130,786 for the year ended December 31, 2019. Additionally, payments to redeem equity securities was $615,014 for the year ended December 31, 2018. There was no such redemption during the year ended December 31, 2019. During the year ended December 31, 2019, the Company made dividend payments of $133,594 to preferred unit holders and $417,885 of principal payments on the insurance financing note. There were no such payments during the year ended December 31, 2018.

Future Capital Requirements

As of December 31, 2019, we had $3,738,900 in cash and cash equivalents.

We expect to continue to incur additional costs associated with operating 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 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.

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

- the terms and timing of any strategic alliance, licensing and other arrangements that Salarius may establish;
- the initiation and progress of Salarius' ongoing pre-clinical studies and clinical trials for its product candidates;
- the number of programs Salarius pursues;
- the outcome, timing and cost of regulatory approvals;

- the cost and timing of hiring new employees to support Salarius' continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of Salarius' product candidates manufactured.

We believe that our cash and cash equivalents currently on hand are sufficient to fund our anticipated operating and capital requirements through at least 12 months from the date this report is filed.

We expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowing and strategic alliances with partner companies. 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. We will need to raise additional capital and may seek to do so through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. 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, 2019 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

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

Application of New Accounting Standards

In February 2016, the Financial Accounting Standards Board (the "FASB") issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 for public entities. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We adopted this guidance effective January 1, 2019 using the following practical expedients:

- we did not reassess if any expired or existing contracts are or contain leases; and
- we did not reassess the classification of any expired or existing leases.

Upon adoption of the new guidance on January 1, 2019, there was no impact on our financial statements.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize right-of-use assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in Salarius' financial instruments and in Salarius' financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2019, Salarius had cash and cash equivalents of $3.7 million. As of December 31, 2019, Salarius' cash was only held in checking and saving accounts. Therefore, Salarius has minimal market risk related to the fair market value of its portfolio.

Item 8. Financial Statements and Supplementary Data

SALARIUS PHARMACEUTICALS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 sheet of Salarius Pharmaceuticals, Inc. (the Company) as of December 31, 2019, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP
We have served as the Company’s auditor since 2019.
Houston, Texas
March 23, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Managers and Members of Salarius Pharmaceuticals, LLC

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Salarius Pharmaceuticals, LLC (the Company) as of December 31, 2018, and the related statement of operations, changes in stockholders' deficit, and cash flows for the year ended December 31, 2018 and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of Salarius Pharmaceuticals, LLC as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP).

Basis for Opinion

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

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

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

/s/ Weaver and Tidwell, L.L.P.

We have served as Salarius Pharmaceutical, LLC's auditor since 2018.

Houston, Texas
March 25, 2019, except for the effects of the recast of equity, to which the date is January 10, 2020.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,738,900	$ 3,228,288
Restricted cash	—	2,903,493
Prepaid expenses and other current assets	955,899	249,086
Total current assets	4,694,799	6,380,867
Property and equipment, net	25,016	37,525
Goodwill	8,865,909	—
Other assets	308,674	195,431
Total assets	$ 13,894,398	$ 6,613,823
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,790,966	$ 379,780
Accrued expenses and other current liabilities	160,783	628,990
Private Salarius accrued series A preferred units	—	2,869,412
Note payable	502,332	—
Deferred revenue	541,701	4,006,755
Warrant liability	317,762	—
Total liabilities	3,313,544	7,884,937
Commitments and contingencies		
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; 4,515,404 and 2,338,899 shares issued at December 31, 2019 and December 31, 2018, and 4,511,174 and 2,032,763 shares outstanding at December 31, 2019 and December 31, 2018, respectively	451	203
Additional paid-in capital	22,657,103	3,869,120
Accumulated deficit	(12,076,700)	(5,140,437)
Total stockholders' equity (deficit)	10,580,854	(1,271,114)
Total liabilities and stockholders' equity (deficit)	$ 13,894,398	$ 6,613,823

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31, 2019	Twelve Months Ended December 31, 2018
Revenue:		
Grant revenue	$ 3,465,055	$ 1,951,351
Operating expenses:		
Research and development	4,018,951	1,287,621
General and administrative	7,711,181	2,348,361
Total operating expenses	11,730,132	3,635,982
Loss before other income (expense)	(8,265,077)	(1,684,631)
Change in fair value of warrant liability	1,311,333	—
Interest income, net	15,648	14,994
Loss from continuing operations	(6,938,096)	(1,669,637)
Income from discontinued operations	1,833	—
Net loss	$ (6,936,263)	$ (1,669,637)
Loss from continuing operations	$ (6,938,096)	$ (1,669,637)
Preferred dividends	—	(123,727)
Loss from continuing operations attributable to common stockholders	$ (6,938,096)	$ (1,793,364)
Loss per common share — basic and diluted		
Continuing operations	$ (2.12)	$ (1.16)
Discontinued operations	—	—
Total net loss per share	$ (2.12)	$ (1.16)
Weighted-average number of common shares outstanding — basic and diluted	3,268,637	1,539,388

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Twelve Months Ended December 31, 2019	Twelve Months Ended December 31, 2018
Operating activities		
Net loss	$ (6,936,263)	$ (1,669,637)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation, amortization and impairment	127,408	16,950
Equity-based compensation expense	751,618	30,961
Change in fair value of warrant liability	(1,311,333)	—
Changes in operating assets and liabilities:		
Accounts receivable	690	—
Inventory	1,169	—
Prepaid expenses and other current assets	91,582	(239,540)
Accounts payable	(519,276)	(285,453)
Accrued expenses and other current liabilities	(320,637)	3,275,259
Deferred revenue	(3,465,054)	3,048,649
Net cash provided by (used in) operating activities	(11,580,096)	4,177,189
Investing activities		
Net cash received in reverse acquisition	5,403,634	—
Net proceeds received from disposal of discontinued operations	204,274	—
Net cash provided by investing activities	5,607,908	—
Financing activities		
Proceeds to redeem equity securities	—	25,000
Proceeds from issuance of equity securities	4,130,786	2,025,269
Payment of dividends	(133,594)	—
Payments to redeem Series 1 preferred units	—	(615,014)
Payments on note payable	(417,885)	—
Net cash provided by financing activities	3,579,307	1,435,255
Net (decrease) increase in cash, cash equivalents and restricted cash	(2,392,881)	5,612,444
Cash, cash equivalents and restricted cash at beginning of period	6,131,781	519,337
Cash, cash equivalents and restricted cash at end of period	$ 3,738,900	$ 6,131,781
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 9,005	$ —
Non-cash investing and financing activities:		
Issuance of shares for license	$ 110,474	$ —
Conversion of liabilities to equity securities	$ 2,869,412	$ —
Issuance of common shares for business combination	$ 11,093,561	$ —
Prepaid expense financed by note payable	$ 920,217	$ —
Intangible assets (License right issued for accrued common stock investment)	$ —	$ 110,474
Dividend payable	$ —	$ 35,713
Series 1 preferred conversion	$ —	$ 1,330,734
Dividend accretion	$ —	$ 26,999

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, 2017	1,178,604	$ 118	$ 570,256	$ (3,470,800)	$ (2,900,426)
Equity-based compensation expense	46,657	4	30,957	—	30,961
Accrued dividend	—	—	(123,727)	—	(123,727)
Net loss	—	—	—	(1,669,637)	(1,669,637)
Issuance of equity securities, net	451,826	45	2,025,224	—	2,025,269
Conversion of Series 1 to Series A	355,676	36	1,366,410	—	1,366,446
Balance at December 31, 2018	**2,032,763**	**203**	**3,869,120**	**(5,140,437)**	**(1,271,114)**
Issuance of equity securities, net	1,711,350	170	6,932,166	—	6,932,336
Issuance of equity securities for license, net	12,907	1	110,473	—	110,474
Equity-based compensation expense	31,586	5	751,613	—	751,618
Distribution to stockholders	—	—	(99,758)	—	(99,758)
Effect of reverse acquisition	722,568	72	11,093,489	—	11,093,561
Net loss	—	—	—	(6,936,263)	(6,936,263)
Balance at December 31, 2019	**4,511,174**	**$ 451**	**$ 22,657,103**	**$ (12,076,700)**	**$ 10,580,854**

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 biotechnology company focused on developing effective epigenetic-based cancer treatments for indications with high unmet medical need. Salarius’ lead epigenetic enzyme technology was licensed from the University of Utah Research Foundation in 2011. The Company is located in Houston, Texas.

Merger with Flex Pharma, Inc.

On January 3, 2019, Flex Pharma, Inc. ("Flex Pharma"), Salarius Pharmaceuticals LLC ("Private Salarius") and Falcon Acquisition Sub, LLC (“Merger Sub”), a wholly owned subsidiary of Flex Pharma, entered into an Agreement and Plan of Merger (the “Merger Agreement”). Pursuant to the Merger Agreement, Merger Sub merged with and into Private Salarius, with Private Salarius continuing as a wholly owned subsidiary of Flex Pharma and the surviving company of the merger. The merger was completed on July 19, 2019. After the merger, Flex Pharma was renamed Salarius Pharmaceuticals, Inc. The merger was accounted for as a reverse acquisition with Private Salarius being deemed the acquiring company for accounting purposes. See Note 3.

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. As of September 30, 2019, the Company had determined that substantial doubt about the Company’s ability to continue as a going concern existed. Subsequently, the Company took into consideration the capital raised during February 2020 (see Note 10). As a result, substantial doubt about the Company’s ability to continue as a going concern for the 12 months from the date of issuance of these financial statements is alleviated.

The Company is subject to risks common to companies in the biotechnology industry and the future success of the Company is dependent on its ability to successfully complete the development of, and obtain regulatory approval for, its product candidates, manage the growth of the organization, obtain additional financing necessary in order to develop, launch and commercialize its product candidates, and compete successfully with other companies in its industry.

As described above, the merger with Flex Pharma closed on July 19, 2019. The merger was accounted for as a reverse acquisition with Private Salarius being deemed the acquiring company for accounting purposes. Private Salarius’ historical financial statements have replaced Flex Pharma’s historical consolidated financial statements with respect to periods prior to the completion of the merger with retroactive adjustments to Private Salarius' legal capital to reflect the legal capital of Flex Pharma. Flex Pharma (renamed Salarius Pharmaceuticals, Inc.) remains the continuing registrant and reporting company. Accordingly, the historical financial and operating data of Salarius Pharmaceuticals, Inc., which covers periods prior to the closing date of the merger, reflects the assets, liabilities and results of operations of Private Salarius and does not reflect the assets, liabilities and results of operations of Flex Pharma Inc. for the periods prior to July 19, 2019, the Company retrospectively adjusted its Statement of Changes in Stockholders’ Equity (Deficit) and the weighted average shares used in determining loss per common share to reflect the conversion of the outstanding common unit, profits interest common unit and Series A Preferred unit of Private Salarius that converted into shares of the Company’s common stock upon the merger, and to reflect the effect of the 25 to 1 reverse stock split of the Company’s common stock which occurred upon the merger.

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.

Cash, Cash Equivalents and Short-Term Investments

Salarius considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. Short-term investments consist of U.S. treasury bills and corporate debt securities. The Company's short-term investments, if any, are classified as available-for-sale securities and are carried at fair value, based on quoted market prices of the securities. The Company views its available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. Unrealized gains and losses on such securities are reported as a separate component of stockholders' equity. Net realized gains and losses, interest and dividends are included in interest income. The cost of securities sold is based on the specific identification method. There were no short term investments as of December 31, 2019 and December 31, 2018.

At December 31, 2019 and December 31, 2018, Salarius held restricted cash of $0 and $2,903,493 for the Series A Preferred proceeds, respectively.

At December 31, 2019 and December 31, 2018, Salarius also held approximately $1.0 million and $4.1 million, respectively, for funds received from Cancer Prevention and Research Institution of Texas ("CPRIT"). These funds are to be used for costs for allowable expenses, primarily research and development expenses. The grant has a mandatory fund matching requirement. Subject to CPRIT review, the Company believes that all matching fund requirements have been met at December 31, 2019.

Intangibles

Intangible assets that have finite useful lives are amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. Intangible assets are included in other assets in the Company's Consolidated Balance Sheets.

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. During the twelve months ended December 31, 2019 and December 31, 2018 impairment charges related to long-lived assets was $110,474 and $0, respectively.

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.

Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The first step in the impairment process is to determine the fair value of the reporting unit and then compare it to the carrying value, including goodwill. If the fair value exceeds the carrying value, no further action is required and no impairment loss is recognized. 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. There was no impairment of goodwill in 2019 or 2018.

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

In conjunction with the reverse merger transaction, the Company issued rights to receive warrants to purchase the Company's common stock. The Company determines whether the 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 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.

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.

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.

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.

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 and the Backsolve method (which is similar to the Black-Scholes valuation model and produces similar results) 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.

Earnings (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 360,234 and 39,945 shares as of December 31, 2019 and 2018, 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, 2019 and December 31, 2018, 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.

Reclassification

Certain reclassifications have been made to the prior-year financial statements to conform to the current-year presentation.

Subsequent Events

The Company’s management reviewed all material events through the date that the financial statements were issued for subsequent event disclosure consideration.

Application of New Accounting Standards

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, “Leases.” ASU 2016-02 requires companies that lease assets to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The pronouncement also requires additional disclosures about the amount, timing and uncertainty of cash flows arising from leases. This pronouncement was effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. This ASU was required to be adopted using a modified retrospective approach. Management adopted ASU 2016-02 on the effective date of January 1, 2019 and elected the practical expedient that allows entities to not apply the new guidance in the comparative periods they present in their financial statements in the year of adoption. Consequently, prior year financial information has not been updated and the disclosures required under the new standard have not been provided for periods prior to January 1, 2019.

Additionally, the Company elected the practical expedients whereby the Company (i) does not recognize right-of-use assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases. The adoption of this ASU on January 1, 2019 did not have a material impact on the Company’s consolidated financial statements.

Pronouncements Not Yet Adopted

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles-Goodwill and Other,” which is intended to simplify the subsequent measurement of goodwill. The pronouncement allows an entity, during its annual or interim goodwill impairment evaluation, to compare the fair value of a reporting unit with its carrying amount. An impairment charge is immediately recognized by which the carrying amount exceeds the fair value. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. The Company does not expect adoption of this ASU to have a material impact on its consolidated financial statements.

NOTE 3. REVERSE ACQUISITION AND DISPOSAL

Reverse Acquisition

On January 3, 2019, Flex Pharma, Private Salarius and Merger Sub entered into the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into Private Salarius, with Private Salarius continuing as a wholly owned subsidiary of Flex Pharma and the surviving company of the merger. The merger was completed on July 19, 2019. After the merger, Flex Pharma was renamed Salarius Pharmaceuticals, Inc. The merger was accounted for as a reverse acquisition business acquisition with Private Salarius being deemed the acquiring company for accounting purposes. Private Salarius, as the accounting acquirer, recorded the assets acquired and liabilities assumed of Flex Pharma in the merger at their fair values as of the acquisition date. Private Salarius' historical financial statements have replaced Flex Pharma's historical consolidated financial statements with respect to periods prior to the completion of the merger with retroactive adjustments to Private Salarius' legal capital to reflect the legal capital of Flex Pharma. Flex Pharma (which was renamed Salarius Pharmaceuticals, Inc. in connection with the merger) remains the continuing registrant and reporting company.

Private Salarius was determined to be the accounting acquirer based on the following facts and circumstances: (1) members of Private Salarius owned approximately 80.7% of the voting interests of the combined company immediately following the closing of the transaction; (2) the majority of the board of directors of the combined company was composed of directors designated by Private Salarius under the terms of the Merger Agreement; and (3) existing members of Private Salarius management became the management of the combined company.

The business purposes of the merger included, among other purposes, obtaining the following potential advantages: (i) the combined organization's resources would be immediately available to support Private Salarius' research on Seclidemstat; and (ii) the public company status would allow the Company greater potential access to additional capital.

At the closing of the merger, each outstanding common unit, profits interest common unit and Series A Preferred unit of Private Salarius converted into shares of the Company's common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a 25 to 1 reverse stock split of the Company's common stock) at the conversion ratio formulae described in the Merger Agreement.

In addition, at the closing of the merger, the Company distributed one right per share of common stock to stockholders of record as of the close of business on July 18, 2019. Each right entitles such stockholders to receive a warrant to purchase shares of the Company's common stock six months and one day following the closing date of the merger. See Note 7.

The Company accounted for the acquisition as a reverse merger using purchase accounting. Because the merger qualifies as a reverse acquisition and given that Private Salarius was a private company at the time of the merger and therefore its value was not readily determinable, the fair value of the merger consideration was deemed to be equal to the sum of the quoted market capitalization of the Company at the merger date, the fair value of the Flex Pharma options that fully vested upon the merger together, and the fair value of the rights to receive warrants that were granted to the pre-merger Flex Pharma stockholders. Total purchase consideration is as follows:

Flex Pharma market capitalization at closing	$	10,963,526
Fair value of rights to warrants		1,629,095
Fair value of Flex Pharma outstanding options on the merger date		132,227
Total purchase consideration	$	12,724,848

The Company recorded all tangible and intangible assets acquired and liabilities assumed at their preliminary estimated fair values on the merger date. The following represents the allocation of the estimated purchase consideration:

Fair value of assets acquired		
Cash	$	5,405,826
Accounts receivable		15,168
Inventory		122,235
Prepaid expense and other current assets		106,319
Goodwill and intangibles		8,937,899
Total fair value of assets acquired		14,587,447
Fair value of liabilities assumed		
Accounts payable, accrued liabilities and other current liabilities		1,862,599
Total fair value of liabilities assumed		1,862,599
Net assets acquired	$	12,724,848

Disposition of HOTSHOT Business

On July 24, 2019, the Company sold specified assets related to the HOTSHOT business to Cliff-Cartwright Corporation, an unrelated party, for cash consideration of $299,135. HOTSHOT was a consumer product that prevents and targets exercise-associated muscle cramps. The Company acquired the HOTSHOT business as a result of the reverse acquisition with Flex Pharma. The transaction was treated as a sale of a business. Details of the transaction are as follows:

Proceeds from sale	$	299,135
Carrying value of tangible assets sold		(135,544)
Carrying value of goodwill and intangible assets sold		(71,990)
Cost incurred related to the sale		(94,861)
Liabilities transferred upon sale		3,260
Total gain on sale of HOTSHOT	$	—

The Company had no assets and liabilities presented as discontinued operations as of December 31, 2019 and December 31, 2018.

Unaudited Pro Forma Disclosure

The following unaudited pro forma financial information summarizes the results of operations for the twelve months ended December 31, 2019 and 2018 as if the merger and disposal described above had been completed as of January 1, 2018. Pro forma information primarily reflects adjustments relating to the reversal of transaction costs. Assuming that the merger had been completed as of January 1, 2018, the transaction costs would have been expensed in the prior period.

	Twelve Months Ended December 31, 2019	Twelve Months Ended December 31, 2018
Revenues	$ 3,465,055	$ 1,951,351
Net loss	(10,865,500)	(21,147,765)
Net loss per share	(3.32)	(6.47)

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2019 and December 31, 2018 consisted of the following:

	December 31, 2019	December 31, 2018
Prepaid clinical trial expenses	$ 202,743	$ 210,333
Prepaid insurance	617,096	16,484
Other prepaid and current assets	136,060	22,269
Total prepaid expenses and other current assets	$ 955,899	$ 249,086

Prepaid insurance is comprised of prepaid directors' and officers' insurance. In July 2019, the Company financed their directors' and officers' insurance premium with a short term note, the principal amount of which is approximately $0.9 million, bearing interest at a rate of of 4.61%. The note payable balance was $502,332 as of December 31, 2019 and is included within Current Liabilities on the Consolidated Balance Sheet.

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 to fund development of LSD 1 inhibitor. This is a 3-year grant award originally expired on May 31, 2019. A six-month extension was approved by CPRIT in May 2019 and an additional six month extension through May, 2020. The grant now expires on May 31, 2020 with extensions available.

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.

The CPRIT grant is subject to funding conditions including a matching funds requirement where the Company will match 50% of funding from the CPRIT grant. As of December 31, 2019, the Company has received an aggregate of $9.6 million from the CPRIT grant and there was $9.1 million of funds available for the Company to draw upon meeting certain requirements. There was no funding received from CPRIT during the twelve months ended December 31, 2019. At December 31, 2019 and December 31, 2018, the Company had deferred revenue of $541,701 and $4,006,755, respectively, related to CPRIT contract.

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, restricted cash, accounts payable and note payable approximate their fair values due to the short-term nature of these instruments.

The following table sets forth a summary of changes in the fair value of Level 3 liabilities, the warrant associated with the Flex Pharma merger measured at fair value on a recurring basis for the twelve months ended December 31, 2019 and 2018:

Description	Balance at December 31, 2018	Established	Change in Fair Value	Balance at December 31, 2019
Warrant liability	$ —	$ 1,629,095	$ (1,311,333)	$ 317,762

The following table identifies the carrying amounts of such liabilities at December 31, 2019:

	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 317,762	$ 317,762
Balance at December 31, 2019	$ —	$ —	$ 317,762	$ 317,762

7. STOCKHOLDERS' EQUITY

The accompanying consolidated statements of stockholders' equity (deficit) and the footnotes to the financial statements have been retroactively adjusted to reflect the equity structure (that is, the number and type of equity interests issued) of Flex Pharma, the legal parent (accounting acquiree) of the merger closed on July 19, 2019, with the retained earnings and other equity balances of Private Salarius before the merger. Private Salarius' equity was restated using the exchange ratio established in the merger agreement to reflect the number of shares of Flex Pharma issued in the merger. Concurrent with the merger, the Company's shareholders approved a 1-for-25 reverse stock split, which became effective on July 19, 2019. Total shares owned by Flex Pharma pre-merger shareholders (net of fractional shares paid in cash) was 722,568 shares after reverse stock-split.

Common Stock

During the twelve months ended December 31, 2019, the Company issued 960,489 common shares (4,035 Series A preferred units and 350 profit interest units of Private Salarius) for $4,377,591 (net of offering cost of $10,617) of which, $2,869,412 was received in advance, in 2018.

On October 24, 2019, the Company entered into a common stock purchase agreement with Aspire Capital, which provides that the Company may offer under certain conditions to Aspire Capital up to an aggregate of $10.9 million of the Company's common shares over 30 months. During the twelve months ended December 31, 2019, the Company issued 750,861 common shares to Aspire Capital, 101,810 shares were issued in consideration for entering into the purchase agreement, and 649,051 shares were issued for cash.

In October 2018, 1,366,448 of Private Salarius' Series 1 preferred units were converted into 355,676 common shares (1,530 Series A preferred units).

In December 2018, the Company agreed to grant an unrelated party 12,907 common shares (91 common units of Private Salarius) to acquire licenses for the DNMT1 inhibitor. The grant was approved in January 2019 and the license was granted in 2018. These common shares were valued at $110,474 based on a third-party valuation report and included in accrued liabilities at December 31, 2018.

Right to Warrants

Pursuant to the Merger Agreement (See Note 3), Flex Pharma distributed one right per share of common stock to stockholders of record as of the close of business on July 18, 2019. Each right entitles such stockholders to receive a warrant to purchase the Company's common shares on January 20, 2020. These warrants are exercisable, in the aggregate, into 142,711 shares of the Company's common stock with a 5-year term from January 20, 2020, and an exercise price of $15.17 per share. The warrants are subject to a cashless exercise, at the option of the Company, at the closing of an issuance and sale of the Company’s common stock in certain qualified financing, upon the closing of which the holders of warrants shall be entitled to receive a number of shares of common stock equal to the greater of two formulae defined by the Merger Agreement, which are based on the volume weighted average price of the Company's common stock during the 10 consecutive trading days ending on the trading day immediately preceding the date of exercise. As a result, the warrants have been classified as a liability.

The Company accounted for these warrants at fair value using Level 3 inputs. The Company determined the fair value of this warrant liability using a Black-Scholes valuation model as the Company believes the value will closely approximate the value from the binomial asset pricing model that consisted of a conditional probability weighted expected return method that values the Company’s equity securities assuming various possible future outcomes to estimate the allocation of value within one or more of the scenarios. Using this method, unobservable inputs included the Company’s equity value, expected timing of possible outcomes, risk free interest rates and stock price volatility.

Variables used in the Black-Scholes model are as follows:

	July 19, 2019	December 31, 2019
Discount rate	1.80 %	1.69 %
Expected life (years)	5.50 years	5.06 years
Expected volatility	96.02 %	105.93 %
Expected dividend	— %	— %

Wedbush Warrant

On July 19, 2019, upon the closing of the merger, the Company elected to issue warrants to purchase 42,928 common shares to Wedbush Securities Inc. ("Wedbush") to satisfy $500,000 of the $1,000,000 success fee payable to Wedbush at the closing of the merger. The remaining $500,000 success fee was paid in cash. These warrants have an exercise price of $18.90 and a 5-year term. As of December 31, 2019, all warrants issued to Wedbush were outstanding.

8. EQUITY-BASED COMPENSATION

Private Salarius' Grants

During the twelve months ended December 31, 2019, the Company granted a total of 8,799 restricted common shares (137 profit interest units of Private Salarius) to two employees and one consultant with a vesting period

ranging from 9 months to 4 years. These common shares have an aggregated fair value of approximately $83,000 that was calculated using the Backsolve method.

During the twelve months ended December 31, 2019, 31,583 shares of common stock for Private Salarius' grants vested. As of December 31, 2019, there were 8,362 unvested restricted common stock issued in the Company.

Compensation expense related to Private Salarius' grants was $53,512 and $30,961 for the twelve months ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was $31,383 of unrecognized compensation cost related to Private Salarius' non-vested grants.

Equity Incentive Plans

The Company has granted options to employees, directors, and consultants under the Flex Pharma Inc. 2015 Equity Incentive Plan (the "2015 Plan"). On July 19, 2019, the Company completed a merger with Flex Pharma and Flex Pharma had fully vested options to purchase 90,279 common shares outstanding as of the date of the merger that continue to be exercisable. 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, 2019, there were 25,145 shares remaining available for the grant of stock awards under the 2015 Plan.

The Company has awarded stock options to its employees, directors and consultants, 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 $642,360 has been estimated with the following assumptions for the year ended December 31, 2019:

Risk-free interest rate	1.61%
Volatility	103.70%
Expected life (years)	5.79
Expected dividend yield	0.00%

The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2019:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	—	$ —	—	$ —
Granted	101,082	8.00		
Options from Flex Pharma	65,151	75.42		
Exercised	—	—		
Forfeited	—	—		
Expired	—	—		
Outstanding at December 31, 2019	166,233	$ 34.42	6.53	$ —
Exercisable at December 31, 2019	84,321	$ 60.09	3.45	$ —

As of December 31, 2019, there was approximately $493,360 of total unrecognized compensation cost 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 2.97 years.

On September 10, 2019, the Company granted 101,082 stock options, in the aggregate, to certain employees, directors and a consultant. These awards vest monthly over 3 months to 4 years as continuous services are provided, and expense is being recognized over this period.

9. INCOME TAX

Private Salarius was organized as a limited liability company and subject to the provisions of Subchapter K of the Internal Revenue Code. As such, Private Salarius was not viewed as a taxpaying entity in any jurisdiction and did not require a provision for income taxes. Each member was responsible for the tax liability, if any, related to its proportionate share of Private Salarius's taxable income. The following table presents a reconciliation of income tax expense (benefit) for the Company subsequent to the closing of the reverse acquisition on July 19, 2019, computed at the statutory federal income tax rate to the effective income tax rate as reflected in the consolidated financial statements:

	December 31, 2019
Federal income tax benefit at statutory rate of 21%	$ (1,456,615)
Stock warrant - fair value adjustment	(275,380)
Transaction costs	232,133
Private Salarius activity	622,660
Other	23,675
Valuation allowance	853,527
Income tax benefit	$ —

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized differently in the financial statements and tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax bases of liabilities and assets using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more-likely-than-not criteria in determining if a valuation allowance should be provided. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during periods in which those temporary differences become deductible.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carryforwards, the Company has provided a 100% valuation allowance on its deferred tax assets at December 31, 2019.

The components of the Company's deferred tax assets (liabilities) at December 31, 2019 are as follow:

Deferred tax assets:	
Net operating loss carryforwards	888,000
Stock-based compensation	70,000
Total deferred tax assets	958,000
Deferred tax liabilities:	
Depreciation	(5,000)
Total deferred tax liabilities	(5,000)
Net deferred tax assets	953,000
Less valuation allowance	(953,000)
Net Deferred tax assets	—

At December 31, 2019, the Company has U.S. federal net operating loss carryforwards of approximately $4,228,318 which are available to reduce future taxable income. Any federal net operating losses generated in 2018

or after will not expire as a result of the Tax Cuts and Jobs Act. The Company does not have any pre-2018 federal loss carryforwards.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The merger between Flex Pharma, Inc. and Salarius, LLC resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code and the federal and state net operating losses and tax credit carryforwards of Flex Pharma, Inc. were written off in full.

10. SUBSEQUENT EVENTS

On February 11, 2020, the Company completed a public offering with total gross proceeds of approximately $11.0 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius. The offering is comprised of 7,101,307 Class A units, priced at a public offering price of $1.15 per unit, with each unit consisting of one share of common stock and a five-year warrant to purchase one share of common stock at an exercise price of $1.15 per share, and 1,246,519 Class B Units, priced at a public offering price of $1.15 per unit, with each unit consisting of one share of Series A convertible preferred stock and a five-year warrant to purchase one share of common stock with and exercise price of $1.15 per share. The convertible preferred stock issued in this transaction includes a beneficial ownership limitation on conversion, but has no dividend rights (except to the extent that dividends are also paid on the common stock). The conversion price of the Series A convertible preferred stock in the offering as well as the exercise price of the warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features.

A total of 8,353,480 shares of common stock, 1,246,519 shares of Series A convertible preferred stock, and warrant to purchase up to 9,599,999 shares of common stock were issued in the offering, including the full exercise to the over-allotment option.

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, 2019, 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. In connection with the audit of our consolidated financial statements as of and for the years ended December 31, 2017 and 2018, we identified a material weakness in our internal control over financial reporting related to the failure to evaluate or identify the accounting implication of various transactions which was mainly due to the lack of accounting personnel with necessary knowledge and experience related to financial reporting. During the year ended December 31, 2019, we designed and implemented processes and

internal controls to remediate this material weakness. We engaged consultants and added accounting personnel, including a Chief Financial Officer and Controller, with necessary knowledge and experience. With the oversight of senior management and our audit committee, we have taken steps to remediate the underlying causes of the material weakness. Based on the foregoing, our management determined that our disclosure controls and procedures were effective as of December 31, 2019.

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, 2019, 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, 2019 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, 2019.

Item 9B. Other Information

Management Changes

On March 18, 2020, Mr. Scott Jordan, who currently serves as our Chief Business Officer, notified us of his intention to resign, effective April 30, 2020. Mr. Jordan's resignation is not the result of any disagreement with our board of directors or the Company on any matter relating to its operations, policies or practices.

In addition, on March 18, 2020, we entered into a Separation and Release Agreement (the "Separation Agreement") with Mr. Jordan in connection with his resignation. Pursuant to the Separation Agreement, Mr. Jordan will receive benefits and payments related to his resignation consisting of (i) a severance payment equal to eleven months of Mr. Jordan's current base salary and (ii) reimbursements for health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 until the earlier of (x) eleven months from the effective date of Mr. Jordan's resignation and (y) the date Mr. Jordan becomes covered under another employer group health plan.

On March 9, 2020, we entered into a Consulting Agreement (the "Consulting Agreement") with Mr. Bruce McCreedy who currently serves as a director on our board of directors. Pursuant to the terms of the Consulting Agreement, Mr. McCreedy shall serve as our interim Chief Scientific Officer from the date of the agreement until September 30, 2020.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be set forth under the captions "Election of Directors – Nominees for Election for a Three-Year Term Until the 2021 Annual Meeting," "Election of Directors – Directors Continuing in Office Until the 2022 Annual Meeting," "Election of Directors – Directors Continuing in Office Until the 2023 Annual Meeting," "Executive Officers," "Information Regarding the Board of Directors and Corporate Governance – Code of Ethics," "Information Regarding the Board of Directors and Corporate Governance – Information Regarding Committees of the Board of Directors – Audit Committee" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement to be filed with the SEC, in connection with our 2020 annual meeting of stockholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2019, and is incorporated in this report by reference. Certain information required by this item concerning executive officers is set forth in Part I of this report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be set forth under the captions "Executive and Director Compensation", "Corporate Governance — Compensation Committee Interlocks and Insider Participation" and "Information Regarding the Board of Directors and Corporate Governance — Non-Employee Director Compensation" in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Executive and Director Compensation — Equity Compensation Plan Information” in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth under the captions “Certain Related-Person Transactions” and “Corporate Governance — Director Independence” in the Proxy Statement and is incorporated herein by reference.

Item 14. Principle Accounting Fees and Services

The information required by this item will be set forth under the caption “Ratification of the Selection of Independent Registered Public Accounting Firm — Principal Accountant Fees and Services” in the Proxy and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(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
2.1^	Agreement and Plan of Merger, dated January 3, 2019, by and among Flex Pharma, Inc., Falcon Acquisition Sub, LLC, and Salarius Pharmaceuticals, LLC		8-K	001-36812 Exhibit 2.1	01/04/2019
2.2	Amendment No. 1 to the Agreement and Plan of Merger, dated June 27, 2019, by and among Flex Pharma, Inc., Falcon Acquisition Sub, LLC, and Salarius Pharmaceuticals, LLC		8-K	001-36812 Exhibit 2.1	07/01/2019
2.3	Waiver No. 1 to the Agreement and Plan of Merger, dated July 18, 2019, by and among Flex Pharma, Inc., Falcon Acquisition Sub, LLC, and Salarius Pharmaceuticals, LLC		8-K	001-36812 Exhibit 2.3	07/22/2019
2.4	Asset Purchase Agreement, dated July 23, 2019, by and among the Registrant, Flex Innovation Group LLC and Cliff-Cartwright Purchase Agreement,		8-K	001-36812 Exhibit 2.1	07/24/2019
3.1	Amended and Restated Certificate Amended and Restated Certificate of Incorporation of the		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 the Certificate of Amendment of Certificate of Incorporation of the Registrant filed		8-K	001-36812 Exhibit 3.1	07/22/2019
3.3	Amended and Amended and Restated Bylaws of the Registrant, effective July 19, 2019 Bylaws of the		8-K	001-36812 Exhibit 3.2	07/22/2019
4.1	Form of Common Stock Certificate of Form of Common Stock Certificate of Registrant		S-1	333-201276 Exhibit 4.1	12/29/2014
4.2	Registration Rights Agreement, dated October 24, 2019, by and between the Registrant and Aspire Capital Fund, Registration Rights Agreement, dated		8-K	001-36812 Exhibit 4.1	10/28/2019
4.3	Form of Indenture between Flex Form of Indenture between Flex Pharma, Inc. and one or more		S-3	333-231010 Exhibit 4.4	04/24/2019
4.4	Form of Form of Common Stock Warrant Agreement and Warrant Certificate between Flex Pharma, Inc. and one or more warrant agents to be		S-3	333-231010 Exhibit 4.6	04/24/2019

4.5	Form of Preferred Form of Preferred Stock Warrant Agreement and Warrant Certificate between Flex Pharma, Inc. and one or more warrant agents to be named. Warrant Agreement and Warrant Certificate between Flex Pharma, Inc. and one or more warrant agents to be named.		S-3	333-231010 Exhibit 4.7	04/24/2019
4.6	Form of Form of Debt Securities Warrant Agreement and Warrant Certificate between Flex Pharma, Inc. and one or more warrant agents to be named. Securities Warrant Agreement and Warrant Certificate between Flex Pharma, Inc. and one or more warrant agents to be named.		S-3	333-231010 Exhibit 4.8	04/24/2019
4.7	Form of Common Stock Purchase Form of Common Stock Purchase Warrant..		S-1/A	333-235879 Exhibit 4.8	02/06/2020
4.8	Form of Preferred Stock Form of Preferred Stock Certificate of Registrant. of Registrant.		S-1/A	333-235879 Exhibit 4.9	02/06/2020
4.9	Description of Registrant's Securities	X			
10.1+	Form of Indemnification Agreement Form of Indemnification Agreement between the Registrant		8-K	001-36812 Exhibit 10.1	07/22/2019
10.2*	Exclusive License Agreement, dated Exclusive License Agreement, dated August 3, 2011, between the University of Utah Research Foundation and		S-4	333-229666 Exhibit 10.1	02/14/2019
10.3*	Exclusive Pharmaceutical Sublicense Agreement, dated November 25, 2016, between HLB LifeScience Co., Ltd. Exclusive Pharmaceutical Sublicense Agreement, dated November 25, 2016,		S-4	333-229666 Exhibit 10.2	02/14/2019
10.4*	Cancer Cancer Research Grant Contract, dated June 1, 2016, between the Cancer Prevention and Research Institute of Texas and Salarius Pharmaceuticals, LLC Grant Contract, dated June		S-4	333-229666 Exhibit 10.3	02/14/2019
10.5+	Amended and Restated Executive Amended and Restated Executive Employment Agreement, dated February 5, 2019, between David J. Arthur and		S-4	333-229666 Exhibit 10.5	02/14/2019
10.6+	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
10.7+	Separation and Release Agreement between Scott Jordan and the Registrant, dated March 18, 2020	X			
10.8+	Offer of Offer of Employment with the Registrant dated September 11, 2019 between Mark Rosenblum and the Registrant with the Registrant		8-K	001-36812 Exhibit 10.1	09/16/2019
10.9+	Consulting Agreement between Bruce McCreedy and the Registrant, dated March 6, 2020	X			
10.10+	Flex Pharma, Inc. 2014 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Flex Pharma, Inc. 2014 Equity Incentive Plan, as		S-1	333-201276 Exhibit 10.2	12/29/2014
10.11+	Flex Flex Pharma, Inc. 2015 Employee Stock Purchase Plan, Inc. 2015 Employee Stock Purchase Plan		S-1/A	333-201276 Exhibit 10.4	01/13/2015
10.12+	Flex Pharma, Inc. 2015 Equity Flex Pharma, Inc. 2015 Equity Incentive Plan Plan		S-1/A	333-201276 Exhibit 10.3	01/13/2015

10.13+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Forms of Stock		10-K	001-36812 Exhibit 10.4	03/24/2015
10.14	Common Stock Purchase Common Stock Purchase Agreement, dated October 24, 2019 between Salarius Pharmaceuticals, Inc. and Aspire Capital		8-K	001-36812 Exhibit 10.1	10/28/2019
21.1	Subsidiaries of the Registrant		S-1	333-235879 Exhibit 21	01/10/2020
23.1	Consent of Ernst & Young LLP	X			
23.2	Consent of Weaver and Tidwell, L.L.P.	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			

^ The schedules and exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

* 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

None.

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 23, 2020

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/ Jonathan P. Northrup *Jonathan P. Northrup*	*Chairman of the Board*	*March 23, 2020*
/s/ David J. Arthur *David J. Arthur*	*Director, President & Chief Executive Officer (Principal Executive Officer)*	*March 23, 2020*
/s/ Mark J. Rosenblum *Mark J. Rosenblum*	*Chief Financial Officer (Principal Financial and Accounting Officer)*	*March 23, 2020*
/s/ Tess Burleson *Tess Burleson*	*Director*	*March 23, 2020*
/s/ Arnold Hanish *Arnold Hanish*	*Director*	*March 23, 2020*
/s/ Paul Lammers *Paul Lammers*	*Director*	*March 23, 2020*
/s/ Bruce McCreedy *Bruce McCreedy*	*Director, Interim Chief Scientific Officer*	*March 23, 2020*
/s/ William K. McVicar *William K. McVicar*	*Director*	*March 23, 2020*