

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2020  
**OR**  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36812

**SALARIUS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**46-5087339**  
(I.R.S. Employer  
Identification Number)

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

(832)834-6992  
Registrant's telephone number, including area code

(Former name, former address and former fiscal year, if changed since last report)

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, \$ 0.0001 par value	SLRX	The Nasdaq Stock Market LLC

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

As of November 9, 2020, there were 19,843,866 shares of common stock outstanding.

**SALARIUS PHARMACEUTICALS, INC.**

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

*The information in this Quarterly Report on Form 10-Q, including the information incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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, goals, timing and other expectations related thereto; the Company's belief as to the potential of its lead compound, SP-2577; 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 ability of seclidemstat to demonstrate drug activity the nature, strategy and focus of the Company; the development and commercial potential of any product candidates; the Company's ability and plan to regain and maintain compliance with Nasdaq's continued listing standards; the Company's expectations as to revenue, cash flow, and expenses; critical accounting policies; the potential impact of the COVID-19 pandemic on the Company's business, operations, cash flow and ability to obtain additional financing; the sufficiency of the Company's cash on hand for future operating and capital requirements; the Company's liquidity position, future capital requirements, and need for, and ability to secure, additional financing; the ability of the Company to access additional financing under the Grant Contract with Cancer Prevention and Research Institute of Texas; the Company's operating losses and ability to continue as a going concern and management plan to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and the Company's decision to engage in any new collaborations or selectively partnering its technology to improve 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 "Part I — Item 1A — Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2019, and under Part II — Item 1A — Risk Factors in this Quarterly Report on Form 10-Q. These risks and uncertainties that could cause actual results to differ materially from expectations or those expressed in these forward-looking statements. 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.*

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited)

	September 30, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,557,813	\$ 3,738,900
Grants receivable from CPRIT	3,212,678	—
Prepaid expenses and other current assets	1,148,667	955,899
Total current assets	13,919,158	4,694,799
Property and equipment, net	15,635	25,016
Goodwill	8,865,909	8,865,909
Other assets	262,509	308,674
Total assets	<u>\$ 23,063,211</u>	<u>\$ 13,894,398</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,195,063	\$ 1,790,966
Accrued expenses and other current liabilities	448,862	160,783
Note payable	761,096	502,332
Deferred revenue	—	541,701
Warrant liability	52,224	317,762
Total liabilities	<u>2,457,245</u>	<u>3,313,544</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; 0 issued and outstanding	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 19,821,716 and 4,519,533 shares issued at September 30, 2020 and December 31, 2019, and 19,818,912 and 4,511,174 shares outstanding at September 30, 2020 and December 31, 2019, respectively	1,981	451
Additional paid-in capital	38,265,391	22,657,103
Accumulated deficit	(17,661,406)	(12,076,700)
Total stockholders' equity	<u>20,605,966</u>	<u>10,580,854</u>
Total liabilities and stockholders' equity	<u>\$ 23,063,211</u>	<u>\$ 13,894,398</u>

See accompanying notes to condensed consolidated financial statements.

**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	2019	2020	2019
Revenue:				
Grant revenue	\$ 1,378,239	\$ 874,949	\$ 3,754,379	\$ 2,426,362
Operating expenses:				
Research and development	1,803,682	1,140,909	4,890,375	2,680,982
General and administrative	1,333,062	3,494,205	4,893,021	5,950,431
Total operating expenses	3,136,744	4,635,114	9,783,396	8,631,413
Loss before other income (expense)	(1,758,505)	(3,760,165)	(6,029,017)	(6,205,051)
Change in fair value of warrant liability	45,103	1,130,848	265,538	1,130,848
Government grants and other income	—	—	179,027	—
Interest income (expense), net	(3,230)	(752)	(254)	18,413
Loss from continuing operations	(1,716,632)	(2,630,069)	(5,584,706)	(5,055,790)
Income from discontinued operations	—	2,348	—	2,348
<b>Net loss</b>	<b>\$ (1,716,632)</b>	<b>\$ (2,627,721)</b>	<b>\$ (5,584,706)</b>	<b>\$ (5,053,442)</b>
<b>Loss per common share — basic and diluted</b>	<b>\$ (0.10)</b>	<b>\$ (0.73)</b>	<b>\$ (0.40)</b>	<b>\$ (1.68)</b>
Weighted-average number of common shares outstanding — basic and diluted	17,968,664	3,605,913	13,833,410	3,002,736

See accompanying notes to condensed consolidated financial statements.

**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)

	Nine Months Ended September 30	
	2020	2019
<b>Operating activities</b>		
Net loss	\$ (5,584,706)	\$ (5,053,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and impairment	12,699	123,174
Equity-based compensation expense	149,660	579,721
Equity-based service expense	25,000	—
Change in fair value of warrant liability	(265,538)	(1,130,848)
Changes in operating assets and liabilities:		
Accounts Receivable	—	690
Inventories	—	1,169
Grants receivable	(3,212,678)	—
Prepaid expenses and other current assets	799,210	(206,956)
Accounts payable	(607,904)	(593,351)
Accrued expenses and other current liabilities	288,079	(235,817)
Due to/from related party	—	(1,517)
Deferred revenue	(541,701)	(2,426,361)
Net cash used in operating activities	(8,937,879)	(8,943,538)
<b>Investing activities</b>		
Cash received in reverse acquisition	—	5,403,634
Proceeds received from disposal of discontinued operations	—	204,274
<b>Net cash provided by investing activities</b>	<b>—</b>	<b>5,607,908</b>
<b>Financing activities</b>		
Proceeds from issuance of equity securities, net	14,810,945	1,508,179
Payment of dividend	—	(133,594)
Proceeds from warrants exercised for cash	636,214	—
Payments on note payable	(690,367)	(171,060)
Net cash provided by financing activities	14,756,792	1,203,525
Net increase (decrease) in cash, cash equivalents and restricted cash	5,818,913	(2,132,105)
Cash, cash equivalents and restricted cash at beginning of period	3,738,900	6,131,781
Cash, cash equivalents and restricted cash at end of period	\$ 9,557,813	\$ 3,999,676
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 6,615	\$ 6,867
Non-cash investing and financing activities:		
Accrued issuance costs for public offering	\$ 12,001	\$ —
Issuance of shares for license	\$ —	\$ 110,474
Conversion of liabilities to equity	\$ —	\$ 2,869,412
Prepaid expense financed by note payable	\$ 949,131	\$ 920,217

See accompanying notes to condensed consolidated financial statements.

**SALARIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2018</b>	<b>2,032,763</b>	<b>\$ 203</b>	<b>—</b>	<b>—</b>	<b>\$ 3,869,120</b>	<b>\$ (5,140,437)</b>	<b>\$ (1,271,114)</b>
Issuance of equity securities	960,489	96	—	—	4,377,495	—	4,377,591
Issuance of equity securities for license	12,907	1	—	—	110,473	—	110,474
Equity-based compensation expense	9,550	1	—	—	35,406	—	35,407
Net loss	—	—	—	—	—	(1,522,076)	(1,522,076)
<b>Balance at March 31, 2019</b>	<b>3,015,709</b>	<b>301</b>	<b>—</b>	<b>—</b>	<b>8,392,494</b>	<b>(6,662,513)</b>	<b>1,730,282</b>
Distribution to stockholders	—	—	—	—	(99,758)	—	(99,758)
Equity-based compensation expense	8,910	1	—	—	6,033	—	6,034
Net loss	—	—	—	—	—	(903,645)	(903,645)
<b>Balance at June 30, 2019</b>	<b>3,024,619</b>	<b>302</b>	<b>—</b>	<b>—</b>	<b>8,298,769</b>	<b>(7,566,158)</b>	<b>732,913</b>
Effect of reverse acquisition	722,568	72	—	—	11,093,489	—	11,093,561
Equity-based compensation expense	8,997	1	—	—	538,279	—	538,280
Net loss	—	—	—	—	—	(2,627,721)	(2,627,721)
<b>Balance at September 30, 2019</b>	<b>3,756,184</b>	<b>375</b>	<b>—</b>	<b>—</b>	<b>19,930,537</b>	<b>(10,193,879)</b>	<b>9,737,033</b>
<b>Balance at December 31, 2019</b>	<b>4,511,174</b>	<b>451</b>	<b>—</b>	<b>—</b>	<b>22,657,103</b>	<b>(12,076,700)</b>	<b>10,580,854</b>
Issuance of equity securities, net	8,353,480	835	1,246,519	125	9,466,206	—	9,467,166
Preferred shares converted to common shares	777,825	78	(777,825)	(78)	—	—	—
Equity-based compensation expense	3,198	—	—	—	38,409	—	38,409
Net loss	—	—	—	—	—	(2,083,816)	(2,083,816)
<b>Balance at March 31, 2020</b>	<b>13,645,677</b>	<b>\$ 1,364</b>	<b>468,694</b>	<b>47</b>	<b>\$ 32,161,718</b>	<b>\$ (14,160,516)</b>	<b>\$ 18,002,613</b>
Warrants exercised for cash	503,230	50	—	—	578,664	—	578,714
Preferred shares converted to common shares	468,694	47	(468,694)	(47)	—	—	—
Equity-based compensation expense	1,843	—	—	—	32,905	—	32,905
Equity-based services expense	18,564	2	—	—	24,998	—	25,000
Net loss	—	—	—	—	—	(1,784,258)	(1,784,258)
<b>Balance at June 30, 2020</b>	<b>14,638,008</b>	<b>1,463</b>	<b>—</b>	<b>—</b>	<b>32,798,285</b>	<b>(15,944,774)</b>	<b>16,854,974</b>
Warrants exercised for cash	50,000	5	—	—	57,495	—	57,500
Issuance of equity securities, net	5,130,390	513	—	—	5,331,265	—	5,331,778
Equity-based compensation expense	514	—	—	—	78,346	—	78,346

Net loss	—	—	—	—	(1,716,632)	(1,716,632)	
<b>Balance at September 30, 2020</b>	<u>19,818,912</u>	<u>1,981</u>	<u>—</u>	<u>—</u>	<u>38,265,391</u>	<u>(17,661,406)</u>	<u>20,605,966</u>

See accompanying notes to condensed consolidated financial statements.



**SALARIUS PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**NOTE 1. ORGANIZATION AND OPERATIONS**

**Nature of Business**

Salarius Pharmaceuticals, Inc. ("Salarius" or the "Company"), together with its subsidiaries, Salarius Pharmaceuticals, LLC, Flex Innovation Group LLC, and TK Pharma, Inc., is a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, the Company is developing treatments for cancers caused by dysregulated gene expression, i.e., genes are incorrectly turned on or off. The field concerned with gene expression regulation is called 'epigenetics'. As cancers are often diseases driven by gene dysregulation, epigenetics is an area of interest for cancer treatment. The Company's lead epigenetic based 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. 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.

**Going Concern and Management's Plan**

Salarius has no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Salarius will require substantial additional capital to fund its research and development expenses related to its oncology drug seclidemstat. Based on Salarius' expected cash requirements, Salarius believes that there is doubt that its existing cash and cash equivalents, including net proceeds from public offerings completed in February and August 2020, will be sufficient to fund its operations through one year from the financial statements issuance date.

The Company believes that its access to the capital markets, along with expected CPRIT funding will be sufficient to fund its operations into the second half of 2021. The Company intends to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

**Risks Related to Covid-19 Pandemic**

The outbreak of COVID-19 has spread worldwide. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, clinical trials or the drug procurement, financing, or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations, and business and those of the third parties on which we rely. See "Special Note About

Coronavirus (COVID-19)" of Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations, and "Risk Factors"

## **NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES**

### ***Basis of Presentation***

The accompanying condensed 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").

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 for the periods prior to July 19, 2019. The Company has 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 condensed 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.

### **Unaudited Interim Financial Information**

The accompanying interim financial statements are unaudited. These unaudited interim financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. These unaudited interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2019 included elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on March 23, 2020. In the opinion of management, the unaudited interim financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2020 and the results of operations for the three and nine months ended September 30, 2020 and 2019. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2019 balance sheet included herein was derived from the audited financial statements, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

### **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 and Cash Equivalents**

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

The Company maintains several bank accounts including an interest-bearing account for funds received from Cancer Prevention and Research Institution of Texas ("CPRIT") funded amount. At September 30, 2020 and

December 31, 2019, the CPRIT bank balance was approximately \$0 and \$1.0 million, respectively. These funds were 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 September 30, 2020.

### **Impairment of Long-Lived Assets**

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment charges related to long-lived assets for the three and nine months ended September 30, 2020. During the three and nine months ended September 30, 2019, impairment charges related to long-lived assets were \$0 and \$110,474, 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 during the three and nine months ended September 30, 2020 or September 30, 2019, respectively.

### **Financial Instruments and Credit Risks**

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and restricted cash. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation ("FDIC"). Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

### **Warrants**

In conjunction with the reverse merger transaction, the Company issued rights to receive warrants to purchase the Company's common stock. Further, on February 11, 2020, the Company issued warrants to purchase the Company's common stock in a registered public offering. 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 Condensed Consolidated Statement of Operations within Change in fair value of warrant liability. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant.

### **Clinical Trial Accruals**

The Company's preclinical and clinical trials are performed by third party contract research organizations (CROs) and/or clinical investigators, and clinical supplies are manufactured by contract manufacturing organizations (CMOs). Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon its assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. The Company's estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies, and may not match the actual services performed by the organizations. This could

result in adjustments to the Company's research and development expenses in future periods. To date the Company has had no significant adjustments.

### **Grants Receivable and Revenue Recognition**

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

### **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 to estimate the fair value of the stock-based compensation and incentive units. Assumptions utilized in these models including expected volatility calculated based on implied volatility from traded stocks of peer companies, dividend yield and risk-free interest rate. Additionally, forfeitures are accounted for in compensation cost as they occur.

### **Loss Per Share**

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

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, (iii) unvested restricted stock, (iv) convertible preferred stock and (v) 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 10,075,278 and 389,488 shares as of September 30, 2020 and 2019, 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 September 30, 2020 and December 31, 2019, 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.

### **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 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.

### **Pronouncements Not Yet Adopted**

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740). The guidance eliminates certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. This guidance also includes guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for annual and interim periods in fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the impact this change will have on its consolidated financial statements.

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

## **NOTE 3. 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, with Flex Pharma deemed the legal acquirer and Private Salarius deemed the accounting acquirer, as described below. 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 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 8.

The Company accounted for the acquisition as a reverse merger using purchase accounting. Because the merger qualified 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	\$	<u>12,724,848</u>

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		<u>14,587,447</u>
Fair value of liabilities assumed		
Accounts payable, accrued liabilities and other current liabilities		1,862,599
Total fair value of liabilities assumed		<u>1,862,599</u>
Net assets acquired	\$	<u>12,724,848</u>

#### Unaudited Pro Forma Disclosure

The following unaudited pro forma financial information summarizes the results of operations for the nine months ended September 30, 2020 and 2019 as if the merger described above had been completed as of January 1, 2019. Pro forma information primarily reflects adjustments relating to the reversal of transaction costs. Assuming that the merger had been completed as of January 1, 2019, the transaction costs would have been expensed in the prior period.

	Nine Months Ended	
	September 30,	
	2020	2019
Revenues	\$ 3,754,379	\$ 2,426,362
Net loss	(5,584,706)	(7,802,709)
Net loss per share	(0.40)	(2.08)

#### NOTE 4. GRANTS RECEIVABLE

Grants receivable represents qualifying costs incurred and there is reasonable assurance that conditions of the grant have been met but the corresponding funds have not been received as of the reporting date. Grants receivable balances are \$3,212,678 and \$0 as of September 30, 2020 and December 31, 2019, respectively.

#### NOTE 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at September 30, 2020 and December 31, 2019 consisted of the following:

	<b>September 30, 2020</b>	<b>December 31, 2019</b>
Prepaid clinical trial expenses	\$ 36,518	\$ 202,743
Prepaid insurance	972,236	617,096
Other prepaid and current assets	139,913	136,060
Total prepaid expenses and other current assets	<u>\$ 1,148,667</u>	<u>\$ 955,899</u>

Prepaid insurance is comprised of prepaid directors' and officers' insurance. In July 2020 and 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 2.49% and 4.61%. The note payable balances, which were included within Current Liabilities on the Condensed Consolidated Balance Sheets, were \$761,096 and \$502,332 at September 30, 2020 and December 31, 2019, respectively.

## **NOTE 6. 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 an exclusive license to an epigenetic enzyme lysine specific demethylase 1 ("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 subject to certain adjustments specified in the agreement, such as 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 of up to \$18.7 million to fund the development of LSD-1 inhibitor. This is a 3-year grant award which originally expired on May 31, 2019. However, the Company was approved for an extension with a contract end date of May 31, 2021.

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 a 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 September 30, 2020, the Company has received an aggregate of \$9.6 million from the CPRIT grant. A portion of the remaining \$9.1 million CPRIT grant was for a castration-resistant prostate study (approximately \$2.6 million). The Company has elected not to pursue this study, and accordingly this amount will no longer be available.

There was no funding received from CPRIT during the nine months ended September 30, 2020. At September 30, 2020 and December 31, 2019, the Company had deferred revenue of \$0 and \$541,701, respectively, related to the CPRIT contract. At September 30, 2020 and December 31, 2019, the Company had grants receivable of \$3,212,678 and \$0, respectively, related to the CPRIT contract.



**NOTE 7. FAIR VALUE OF FINANCIAL INSTRUMENTS**

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

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

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

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

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

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 three and nine months ended September 30, 2020:

Description	Balance at December 31, 2019	Change in Fair Value	Balance at September 30, 2020
Warrant liability	\$ 317,762	\$ (265,538)	\$ 52,224

**NOTE 8. STOCKHOLDERS' EQUITY**

The accompanying condensed consolidated statements of stockholders' equity (deficit) and the footnotes to the interim 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 the 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 fraction shares paid in cash) was 8,353,480 shares after reverse stock-split.

**Preferred Stock and Common Stock**

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 "February Offering"). The February Offering was 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 an exercise price of \$1.15 per share. A total of 8,343,480 shares of common stock, 1,246,519 shares of Series A convertible preferred stock, and warrants to purchase up to 9,599,999 shares of common stock were issued in the offering, including the full exercise of the over-allotment option. 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 issued in the February 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.

As of September 30, 2020, all 1,246,519 shares of Series A convertible preferred stock were converted to common stock.

On August 3, 2020, the Company completed a public offering with total gross proceeds of approximately \$6.2 million, which includes the full exercise of the underwriter's over-allotment option to purchase an additional 669,181 shares prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius. A total of 5,130,390 common shares of common stock were issued in the offering, priced at a public offering price of \$1.20 per share.

During the nine months ended September 30, 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).

In December 2018, the Company agreed to issue an unrelated party 12,907 common shares (91 common units of Private Salarius) to acquire licenses for the DNMT1 inhibitor. The issuance was approved in January 2019 and the license was granted in 2018.

### Warrants Exercised for Cash

During the nine months ended September 30, 2019, the Company issued 553,230 common shares as a result of warrant exercises, and received cash proceeds of approximately \$0.6 million. As of September 30, 2020, 9,046,769 of warrants issued in the February Offering were still outstanding.

### 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. 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:

	September 30, 2020	December 31, 2019
Discount rate	0.22%	1.69%
Expected life (years)	4.31 years	5.06 years
Expected volatility	125.28%	103.07%
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 September 30, 2020, all warrants issued to Wedbush were outstanding.

**NOTE 9. EQUITY-BASED COMPENSATION**

**Equity Incentive Plans**

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). 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 and 34,385 of these options continue to be exercisable as of September 30, 2020. 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 September 30, 2020, there were 830,348 shares remaining available for the grant of stock awards under the 2015 Plan.

On March 23, July 14 and September 16, 2020, the Company awarded 182,000 , 541,118 and 20,000 respectively, of stock options to its employees and directors, pursuant to the plan described above. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants of \$92,007, \$623,561 and \$15,679 has been estimated with the following assumptions on the grant date.

	3/23/2020	7/14/2020	9/16/2020
Risk-free interest rate	0.48 %	0.37 %	0.38 %
Volatility	113.17 %	124.20 %	125.42 %
Expected life (years)	5.80	6.00	6.00
Expected dividend yield	0 %	0 %	0 %

The following table summarizes stock option activity for employees and non-employees for the nine months ended September 30, 2020:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	166,233	\$34.42	6.53	\$—
Granted	743,118	0.98		
Forfeited	(36,613)	—		
Expired	(30,766)			
Outstanding at September 30, 2020	841,972	\$4.55	9.32	\$—
Exercisable at September 30, 2020	69,813	\$37.84	5.43	\$—

As of September 30, 2020, there was approximately \$358,869 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 3.3 years.

#### **NOTE 10 PAYROLL PROTECTION PROGRAM**

On April 13, 2020, the Company was granted a loan of approximately \$0.18 million from the Paycheck Protection Program ("PPP") established under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). The loan matures on April 13, 2022 and bears interest at a rate of 1% per annum. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The proceeds of the loan were used in full to pay for payroll disbursement after it was received, which the Company expects to comply with the PPP eligibility and loan forgiveness criteria. As such, the loan was accounted as a government grant at September 30, 2020. The Company will continually reassess its ability to meet the forgiveness conditions, and it may have to reverse income if it can no longer support a conclusion that it expects to meet the conditions.

#### **NOTE 11. SUBSEQUENT EVENTS**

On October 5, 2020 the Company was notified by Nasdaq Stock Market that on October 4, 2020 the average closing price of the Company's common stock over the prior 30 consecutive trading days had fallen below \$1.00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1). The Company intends to actively monitor the closing bid price of its common stock and will evaluate available options to regain compliance with the requirement.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as our audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 23, 2020. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Part I - Item 1A - Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2019, for the year ended December 31, 2019, filed with the SEC on March 23, 2020, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.*

### **Overview**

We are a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, we are developing treatments for cancers caused by dysregulated gene expression, i.e., genes are incorrectly turned on or off. The field concerned with gene expression regulation is called 'epigenetics'. As cancers are often diseases driven by gene dysregulation, epigenetics is an area of interest for cancer treatment. Our lead epigenetic based technology, seclidemstat (SP-2577), may treat cancers by restoring correct gene expression.

SP-2577, which we call seclidemstat, was licensed from the University of Research Foundation in 2011. SP-2577 is a small molecule that inhibits the epigenetic enzyme lysine specific demethylase 1 ("LSD1"). 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 (protein-protein interactions), independently of its enzymatic function, to alter gene expression and modulate cell fate. In healthy cells, LSD1 is necessary for stem cell maintenance and normal cell development processes. However, in several cancers LSD1 is highly expressed and acts 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 tumor growth. We believe the SP-2577 molecule helps inhibit EWS-FLI activity by disrupting EWS-FLI from associating with LSD1 and other proteins that are necessary for its cancer promoting activity. Therefore, we believe that SP-2577 can potentially reverse the cancer promotion gene expression and thereby possibly prevent Ewing sarcoma tumor growth and promote cancer cell death. Preclinical studies of SP-2577 in certain Ewing sarcoma animal models showed 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. We recently announced that we plan to amend the Ewing sarcoma trial to also include up to 30 Ewing-related sarcoma patients upon reaching the dose expansion phase.

As LSD1 can interact 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 1/2 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, we are conducting preclinical work with SP-2577 for use in hematologic cancers.

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 \$17,661,406 as of September 30, 2020. 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.

Our financial statements are prepared using Generally Accepted Accounting Principles in the United States of America ("GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern.

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 September 30, 2020, the Cancer Prevention and Research Institution of Texas ("CPRIT") fund matching requirements had been fully met. As of September 30, 2020, we have received an aggregate of \$9.6 million from the CPRIT grant. A portion of the remaining \$9.1 million CPRIT grant was for a castration-resistant prostate study (approximately \$2.6 million). The Company has elected not to pursue this study, and accordingly this amount will no longer be available. The Company was approved for an extension with a contract end date of May 31, 2021.

We believe that our \$9.6 million in cash and cash equivalents on hand as of September 30, 2020, and the expected CPRIT funds available are sufficient to fund our anticipated operating and capital requirements into the second half of 2021, 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 as a whole. 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 and to fund our operations.

We intend, when required, 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 favorable terms or on terms acceptable to us.

## **Recent Developments**

On July 29, 2020, the Company announced the expansion of its ongoing clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma to include additional select sarcomas that share a similar biology to Ewing sarcoma, also known as Ewing-related sarcomas. The amendment to the ongoing clinical trial will allow patients with Ewing-related sarcomas, which share a similar gene rearrangement to Ewing sarcoma, to enroll in the ongoing trial. Sarcomas of interest include myxoid liposarcoma, desmoplastic small round cell tumors and other sarcomas with FET family translocations, i.e. Ewing-related sarcomas.

Seclidemstat's potential as a treatment for Ewing-related sarcomas is supported by pre-clinical data and early clinical data observations from the ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma. A refractory Ewing sarcoma patient treated with seclidemstat for six months demonstrated a reduction in prospectively defined target lesions. Target lesions generally represent a patient's largest measurable tumors. However, at eight weeks, an increase in non-target lesions resulted in an overall patient classification of progressive disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST).

### **Special Note About Coronavirus (COVID-19)**

The COVID-19 pandemic is significantly affecting the United States, global economies, and businesses worldwide. While the potential magnitude and duration of the economic and social impact of the COVID-19 pandemic is difficult to assess or predict, the impact on the global financial markets may, in the future, reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The COVID-19 pandemic could also have a material and negative impact on our liquidity, capital resources (including our ability to secure additional financing if and when needed), our business and operations, and our workforce, as well as those of the third parties with which we do business or upon which we rely. While, the situation is fluid and we do not yet know the full extent of potential delays or impacts on us or on healthcare systems or the global economy in general, Salarius has worked to adapt to the unexpected and challenging circumstances resulting from the COVID-19 pandemic and at this time we are experiencing minimal COVID-19 disruptions to our clinical programs, our manufacturing capabilities, or our financing capabilities. However, we may experience disruptions in the future that have and could further adversely impact our business operations as well as our preclinical studies and clinical trials.

At this time we are experiencing minimal disruption to our clinical trials. However, our ongoing Phase 1/2 Ewing sarcoma clinical trial and Phase 1/2 AST clinical trial can each enroll up to 50 patients and in the future we may encounter delays in enrolling new patients due to concerns or healthcare resource constraints as a result of the COVID-19 pandemic. In addition, although at this time we have experienced no disruptions to manufacturing capabilities, certain aspects of our supply chain may be disrupted as certain of our third party suppliers and manufacturers have paused their operations in response to the COVID-19 pandemic or have otherwise encountered delays in providing supplies and services. We continue to evaluate the extent to which these delays will impact our ability to manufacture our product candidates for our clinical trials and conduct other research and development operations and maintain applicable timelines. The ultimate impact of the COVID-19 pandemic on our business operations as well as our preclinical studies and clinical trials remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We will continue to monitor the situation closely.

## Results of Operations

### Three Months Ended September 30, 2020 Compared to the Three Months Ended September 30, 2019

The following table sets forth the condensed consolidated results of our operations for the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

	Three months ended September 30		Effect on Net Loss <sup>(a)</sup>	
	2020	2019	\$	%
Grant revenue	\$ 1,378,239	\$ 874,949	\$ 503,290	58 %
Research and development expenses	(1,803,682)	(1,140,909)	(662,773)	(58)%
General and administrative expenses	(1,333,062)	(3,494,205)	2,161,143	62 %
Change in fair value of warrant liability	45,103	1,130,848	(1,085,745)	(96)%
Interest expense	(3,230)	(752)	(2,478)	(330)%
Income from discontinued operations	—	2,348	(2,348)	(100)%
Net loss	<u>\$ (1,716,632)</u>	<u>\$ (2,627,721)</u>	<u>\$ 911,089</u>	<u>35 %</u>

Note a - Positive numbers reduce net loss, negative numbers increase net loss.

#### Grant Revenue

Grant revenue, which was derived solely from the CPRIT grant, was \$1,378,239 during the three months ended September 30, 2020 compared to \$874,949 during the three months ended September 30, 2019. 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.

#### Research and Development Expenses

Research and development expenses were \$1,803,682 during the three months ended September 30, 2020 compared to \$1,140,909 during the three months ended September 30, 2019. The 58% net increase of \$662,773 was primarily due to the manufacturing of our active pharmaceutical ingredient in preparation of forecasted increased enrollment and clinical trial activity and higher personnel and consulting fees offsetting lower clinical trial spending.

#### General and Administrative Expenses

General and administrative expenses were \$1,333,062 for the three months ended September 30, 2020 compared to \$3,494,205 for the three months ended September 30, 2019. During the 2019 period the Company incurred significant one-time legal and professional service costs from the transformation into a public company during July 2019. In the current period, an increase in payroll expense was offset by a decrease in legal and travel expenses.

#### Change in Fair Value of Warrant Liability

The change in fair value of warrant liability of \$45,103 was primarily due to the fluctuation of the price of our common stock (\$1.32 per share on June 30, 2020 compared to \$.84 per share on September 30, 2020). We recognized a gain of \$45,103 due the change in fair value of warrant liability during the three months ended September 30, 2020.

### Nine Months Ended September 30, 2020 Compared to the Nine Months Ended September 30, 2019

The following table sets forth the condensed consolidated results of our operations for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.



	Nine months ended September 30		Effect on Net Loss <sup>(a)</sup>	
	2020	2019	\$	%
Grant revenue	\$ 3,754,379	\$ 2,426,362	\$ 1,328,017	55 %
Research and development expenses	(4,890,375)	(2,680,982)	(2,209,393)	(82)%
General and administrative expenses	(4,893,021)	(5,950,431)	1,057,410	(18)%
Change in fair value of warrant liability	265,538	1,130,848	(865,310)	(77)%
Government grants and other income	179,027	—	179,027	100 %
Interest income(expense), net	(254)	18,413	(18,667)	(101)%
Income from discontinued operations	—	2,348	(2,348)	(100)%
<b>Net loss</b>	<b>\$ (5,584,706)</b>	<b>\$ (5,053,442)</b>	<b>\$ (531,264)</b>	<b>(11)%</b>

Note a - Positive numbers reduce net loss, negative numbers increase net loss.

### **Grant Revenue**

Grant revenue, which was derived solely from the CPRIT grant, was \$3,754,379 during the nine months ended September 30, 2020 compared to \$2,426,362 during the nine months ended September 30, 2019. 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.

### **Research and Development Expenses**

Research and development expenses were \$4,890,375 during the nine months ended September 30, 2020 compared to \$2,680,982 during the nine months ended September 30, 2019. The 82% increase of \$2,209,393 was primarily related to increased clinical trial and consulting fees related to the increased number of patients enrolled across additional clinical trial sites. Manufacturing expense significant increased during the current period resulting from increased production of active pharmaceutical ingredient.

### **General and Administrative Expenses**

General and administrative expenses were \$4,893,021 for the nine months ended September 30, 2020 compared to \$5,950,431 for the same period a year ago. a decrease of \$1,057,410. During the current period significant higher personnel related expenses and increased director & officers insurance costs were more than offset by lower professional fees and cost associated with July 2019 merger and transformation into a public company that did not recur in the current period.

### **Change in Fair Value of Warrant Liability**

The change in fair value of warrant liability of \$265,538 was primarily due to the fluctuation of the price of our common stock (\$3.78 per share on December 31, 2019 compared to \$.84 per share on September 30, 2020). We recognized a gain of \$265,538 due the change in fair value of warrant liability during the nine months ended September 30, 2020 .

## **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 solely from CPRIT grant.

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.

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

Based on our expected cash requirement, we believe that there is substantial doubt that our existing cash and cash equivalents will be sufficient to fund our operation through one year from the date of this report. See also "Risk Factors".

As of September 30, 2020, we had \$11,461,913 of working capital and our cash and cash equivalents totaled \$9,557,813, which were held in bank deposit accounts and money market funds. Our cash and cash equivalents balance increased during the nine months ended September 30, 2020, primarily due to our public offering which closed on February 11 and August 3, 2020.

### **Cash Flows**

	<b>Nine months ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
Net cash (used in) provided by in:		
Operating activities	\$ (8,937,879)	\$ (8,943,538)
Investing activities	—	5,607,908
Financing activities	14,756,792	1,203,525
Net increase (decrease) in cash and cash equivalents	<u>\$ 5,818,913</u>	<u>\$ (2,132,105)</u>

### **Operating Activities**

Net cash used in operating activities was \$8,937,879 and \$8,943,538 for the nine months ended September 30, 2020 and September 30, 2019, respectively. Our receivable from CPRIT increased \$3.2 million in the current period reflecting unreimbursed CPRIT allowable cash spending.

### **Financing Activities**

Net cash provided by financing activities for the nine months ended September 30, 2020 was \$14,756,792, compared to \$1,203,525 for the same period of the year 2019. The increase of cash provided by financing activities resulted from the Company's completion of public offerings on February 11 and August 3, 2020 with net proceeds of approximately \$14.8 million, and the receipt of approximately \$0.6 million cash from the warrant exercised during the nine month ended September 2020. These increases were partially offset by the payment of \$690,367 towards the principal on an insurance financing note.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed 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 condensed 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 condensed consolidated financial statements prospectively from the date of the change in estimate.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K filed with SEC on March 23, 2020.

Readers should refer to our Annual Report on Form 10-K filed with SEC on March 23, 2020, Note 2, Basis of Presentation and Significant Accounting Policies to the accompanying financial statements for descriptions of these policies and estimates.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the Exchange Act with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer and principal accounting officer), as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial and accounting officer) have concluded that, as of such date, our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

During the three and nine months ended September 30, 2020, there was no significant change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not a party to any material legal proceedings on the date of this report. We may from time to time become involved in legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

**Item 1A. Risk Factors**

For a discussion of certain factors that could materially affect our business, financial condition, and operating results, you should carefully review and consider the information under “Part I, Item 1A- Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 23, 2020, as well as the risk factors set forth below. The risk factors below are in addition to and supplement (and with respect to certain matters, update) the risk factors discussed in our Annual Report on Form 10-K and in our Current Report on Form 8-K filed on July 29, 2020. Other than as set forth below, there have been no material changes to the risk factors included in our Annual Report on Form 10-K filed with the SEC on March 23, 2020 and in our Current Report on Form 8-K filed on July 29, 2020.

## **Risks Related to Our Business and Our Industry**

### ***The COVID-19 pandemic could adversely affect our business, results of operations, and financial condition.***

To date, the COVID-19 pandemic has negatively impacted the global economy and the magnitude, severity, and duration of this impact is unclear and difficult to assess. In addition, certain areas, including Texas where we are headquartered, have recently experienced a resurgence of COVID-19 cases. We have worked to adapt to the unexpected and challenging circumstances resulting from the COVID-19 pandemic and we have experienced minimal COVID-19 disruptions to our clinical programs, our manufacturing capabilities and our financing capabilities during the nine months ended September 30, 2020. Both our Ewing sarcoma clinical study and our Advanced Solid Tumor clinical study are active and continue to enroll patients. We plan to release clinical data from both studies, as previously disclosed, during 2020 and 2021. However, the situation with respect to the COVID-19 pandemic and its impact changes daily and is difficult to predict.

To combat the spread of COVID-19, the United States and other locations in which we operate have imposed measures such as quarantines and “shelter-in-place” orders that are restricting business operations and travel and requiring individuals to work from home (“WFH”), which has impacted all aspects of our business as well as those of the third-parties we rely upon for certain supplies and services. The continuation of WFH and other restrictions for an extended period of time may negatively impact our productivity, research and development, operations, preclinical studies and clinical trials, business and financial results. Among other things, the COVID-19 pandemic may result in:

- a global economic recession or depression that could significantly and negatively impact our business or those of third parties upon which we rely for services and supplies;
- constraints on our ability to conduct our operations and our preclinical studies and clinical trials;
- delays in our ability to extend the term of the CPRIT grant;
- reduced productivity in our business operations, research and development, marketing, and other activities;
- disruptions to our third-party manufacturers and suppliers;
- increased costs resulting from WFH or from our efforts to mitigate the impact of COVID-19; and
- reduced access to financing to fund our operations due to a deterioration of credit and financial markets.

We continue to monitor the situation and the continued disruption of the COVID-19 pandemic and its effects on the worldwide economy could negatively and materially impact our operating and financial operating results. The resumption of normal business operations may be delayed and a resurgence of COVID-19 could occur resulting in continued disruption to us or to the third parties with which we do business. As a result, the effects of the COVID-19 pandemic could have a material adverse impact on our business, results of operations, and financial condition for the remainder of 2020 and beyond.

## **Risks Related to Salarius’ Financial Condition and Capital Requirements**

### ***Substantial doubt exists as to our ability to continue as a going concern***

We have no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company’s ability to continue as a going concern. The financial statements accompanying this report are prepared using accounting principles

generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. We will require substantial additional capital to fund our research and development expenses related to our oncology drug Secclidemstat.

As of September 30, 2020, we had an accumulated deficit of \$17.7 million, cash and cash equivalents of \$9.6 million, and current liabilities of \$2.5 million. Based on available resources, we believe that our cash and cash equivalents currently on hand are sufficient to fund our currently anticipated operating and capital requirements into the second half of 2021. Thus, our current capital resources are not sufficient to fund our planned operations for the next 12 months from the date of the financial statements included in this report. Moreover, we have not established a source of revenue and we expect to continue to incur losses for the foreseeable future as we continue our development of, and seek marketing approvals for, our product candidates. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern and therefore it may be more difficult for us to attract investors. Unless we are able to raise additional capital to finance our operations, our long-term business plan may not be accomplished, and we may be forced to cease, reduce, or delay operations.

***We will continue to require substantial additional capital to fund our clinical activities and operations and the impact of the COVID-19 pandemic on the financial markets will likely negatively impact our ability to raise additional financing.***

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. We have never been profitable and have incurred operating losses in each year since inception. Our net losses were \$6.9 million for the year ended December 31, 2019, and we have incurred net loss of \$1.7 million and \$5.6 million for the three and the nine months ended September 30, 2020, respectively. 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 development of our product candidates have been funded in part through federal and state grants, including, but not limited to, the funding received from CPRIT. The amount and timing of our future funding requirements will depend on many factors, including but not limited to the pace and results of our clinical development efforts, as well as our ability to access the funding remaining available under the CPRIT grant. To date, we have also financed our operations primarily through the sale of equity securities. Our stock price has been negatively impacted in part by the downturn in the financial markets due to the COVID-19 pandemic. This in turn will likely negatively impact our ability to raise funds through equity-related financings. Further, the global economic downturn may impair our ability to obtain additional financing through other means, such as debt financing. There can be no assurance we will be able to secure additional financing on favorable terms to us, or at all. Further any debt financing may contain restrictive covenants which limit our operating flexibility and any equity financing will likely result in additional and possibly significant dilution to existing stockholders. Failure to raise sufficient capital, as and when needed or on commercially reasonable terms, would have a significant and negative impact on our financial condition and our ability to develop our product candidates.

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

To the extent that we raise additional capital through the sale of equity, convertible debt, or other securities convertible into equity, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our equity holders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to its product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We may not be able to obtain additional funding when necessary to fund our entire portfolio of product candidates to meet its projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations

or otherwise capitalize on potential business opportunities. The occurrence of any of these events could materially harm our business, financial condition, and results of operations.

***We rely on federal and state grants, including funding from CPRIT and failure to receive additional grants may harm our business.***

During the course of the development of our product candidates, we have been funded in part through federal and state grants, including but not limited to the funding we received from CPRIT. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, including under the risk factor entitled “Reliance on government funding for our 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 our business, financial condition and results of operations.” The CPRIT agreement was awarded in June 2016 and originally provided for a three-year grant award of up to \$18.7 million to fund the development of the LSD-1 inhibitor. As of March 31, 2020, we had received an aggregate of \$9.6 million from the CPRIT grant. A portion of the remaining \$9.1 million CPRIT grant was for a castration-resistant prostate study (approximately \$2.6 million). The Company elected not to pursue this study and accordingly this amount will no longer be available. If CPRIT terminates our agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us to repay some or all of the disbursed grant. The term of the CPRIT agreement was extended through November 30, 2020 and we were approved for an extension through May 31, 2021. Although we may apply for government contracts and grants in the future, we may not be successful in obtaining additional grants for any product candidates or programs. Failure to receive government grants in the future may harm our business.

**Risks Related to Salarius’ Reliance on Third Parties**

***If we fail to comply with the continued listing standards of Nasdaq, our common stock may be delisted from Nasdaq. This in turn could result in significantly reduced trading liquidity, reduced trading volumes, and loss of research analyst coverage, among other consequences. These in turn could result in a further decline in the market price of common stock and would have a material adverse effect on our company.***

On October 5, 2020, we were notified (the “Notice”) by Nasdaq Stock Market, LLC (“Nasdaq”) that on October 4, 2020 the average closing price of our common stock over the prior 30 consecutive trading days had fallen below \$1.00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the “Minimum Bid Requirement”). In accordance with Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days to regain compliance with the Minimum Bid Requirement (the “Compliance Date”). To regain compliance, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days on or before the Compliance Date. If we do not regain compliance with the Minimum Bid Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period

In addition to continuing to monitor the closing bid price of our common stock, we expect to consider available options to regain compliance with the Minimum Bid Requirement. However, we cannot assure you that we will continue to comply with the continued listing standards of Nasdaq. To the extent that we are unable to maintain listing compliance or are unable to resolve any listing deficiency in the future, 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.

If, for any reasons, Nasdaq should delist our common stock, and if our common stock is not then eligible for quotation on another market for exchange, trading of shares of our common stock could be conducted in the over-the-counter markets. In such event, a reduction in some or all of the following may occur, each of which could materially and 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.

The occurrence of any of these events could result in a further decline in the market price of common stock and could have a material adverse effect on us.

**Item 6. Exhibits**

<b>Exhibit number</b>	<b>Description of Document</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2015).</a>
3.2	<a href="#">Certificate of Amendment of Certificate of Incorporation, filed with Secretary of State of Delaware on July 18, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).</a>
3.3	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated February 10, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 12, 2020).</a>
3.4	<a href="#">Amended and Restated Bylaws, effective July 19, 2019 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).</a>
4.1	<a href="#">Common Stock Purchase Warrant dated February 11, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 12, 2020).</a>
4.2	<a href="#">Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-1/A filed on February 6, 2020).</a>
4.3	<a href="#">Form of Preferred Stock Certificate of Registrant (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-1/A filed on February 6, 2020).</a>
31.1	<a href="#">Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
31.2	<a href="#">Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
32.1*	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</a>
101.0	The following materials from Salarius Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (eXtensible Business Reporting Language):(i) Unaudited Condensed Consolidated Balance Sheets, (ii) Unaudited Condensed Consolidated Statements of Operations (iii) Unaudited Condensed Consolidated Statements of Stockholders' Equity (Deficit), (iv) Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Unaudited Consolidated Financial Statements.

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\* The material contained in Exhibit 32.1 is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filing, except to the extent that the registrant specifically incorporates it by reference.



**SIGNATURES**

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

**SALARIUS PHARMACEUTICALS, INC.**

By: /s/ David J. Arthur  
David J. Arthur  
*President and Chief Executive Officer (Principal Executive Officer)*

By: /s/ Mark J. Rosenblum  
Mark J. Rosenblum  
*Chief Financial Officer and Executive Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)*

Date: November 12, 2020

**Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, David J. Arthur, President and Chief Executive Officer, certify that:

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

/s/ David J. Arthur

David J. Arthur

President and Chief Executive Officer (Principal Executive Officer)

November 12, 2020

**Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Mark J. Rosenblum, Executive Vice President and Interim Chief Financial Officer, certify that:

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

/s/ Mark J. Rosenblum

Mark J. Rosenblum

Executive Vice President and Interim Chief Financial Officer  
(Principal Financial and Accounting Officer)

November 12, 2020

**Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of Salarius Pharmaceuticals, Inc. (the "Company") for the fiscal period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

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

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

November 12, 2020

/s/ David J. Arthur

David J. Arthur

President and Chief Executive Officer (Principal Executive Officer)

November 12, 2020

/s/ Mark J. Rosenblum

Mark J. Rosenblum

Executive Vice President and Interim Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)