# 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 June 30, 2021

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  $\boxtimes$  No  $\square$ 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  $\boxtimes$  No  $\square$ 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  $\square$  Accelerated Filer  $\square$  Non-accelerated Filer  $\boxtimes$  Smaller Reporting Company  $\boxtimes$  Emerging Growth Company  $\square$ 

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 August 2, 2021, there were 44,778,794 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 and exhibits incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements other than statements of historical fact constitute forward-looking statements. 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, and intellectual property; 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 Nasdag's continued listing standards; the Company's expectations as to revenue, cash flow, and expenses; the potential impact of the COVID-19 pandemic on the Company's business, operations, cash flow and ability to obtain additional financing; the Company's liquidity position, the expected sufficiency of such position for anticipated operating and capital requirements; 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 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, 2020, 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," "target", "potential," "evaluate," "proceeding" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements.

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

## **PART I - FINANCIAL INFORMATION**

## Item 1. Financial Statements

## SALARIUS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

		6/30/2021 (Unaudited)	 12/31/2020
Assets			
Current assets:			
Cash and cash equivalents	\$	33,079,389	\$ 11,118,614
Grants receivable from CPRIT		4,794,919	3,855,996
Prepaid expenses and other current assets		432,502	 822,050
Total current assets		38,306,810	 15,796,660
Property and equipment, net		15,260	22,639
Other assets		216,786	247,113
Goodwill		8,865,909	 8,865,909
Total assets	\$	47,404,765	\$ 24,932,321
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	\$	1,275,879	\$ 1,853,756
Accrued expenses and other current liabilities		214,677	383,138
Note payable		—	477,028
Warrant liability		63,079	59,211
Total liabilities		1,553,635	 2,773,133
Commitments and contingencies (Note 5)			
Stockholders' equity:			
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; 0 issued and outstanding	g	_	_
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 44,778,794 and 23,810,541 shares issued at June 30, 2021 and December 31, 2020, and 44,778,794 and 23,808,546 shares outstanding at June 30, 2021 and December 31, 2020, respectively		4,477	2,381
Additional paid-in capital		70,201,872	41,585,761
Accumulated deficit		(24,355,219)	 (19,428,954)
Total stockholders' equity		45,851,130	 22,159,188
Total liabilities and stockholders' equity	\$	47,404,765	\$ 24,932,321

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30				Six Months Ended June 30			
		2021		2020		2021		2020
Revenue:								
Grant revenue	\$	571,387	\$	1,243,310	\$	1,840,216	\$	2,376,140
Operating expenses:								
Research and development		2,096,302		1,443,322	\$	3,836,957		3,086,693
General and administrative		1,591,905		1,700,942		2,924,674		3,559,959
Total operating expenses		3,688,207		3,144,264		6,761,631		6,646,652
Loss before other income (expense)		(3,116,820)		(1,900,954)		(4,921,415)		(4,270,512)
Change in fair value of warrant liability		42,186		(62,635)		(3,868)		220,435
Government grants and other income				179,027		_		179,027
Interest income (expense), net		265		304		(982)		2,976
Loss from continuing operations		(3,074,369)		(1,784,258)		(4,926,265)		(3,868,074)
Net loss	\$	(3,074,369)	\$	(1,784,258)	\$	(4,926,265)	\$	(3,868,074)
Loss per common share — basic and diluted	\$	(0.07)	\$	(0.13)	\$	(0.13)	\$	(0.33)
Weighted-average number of common shares outstanding — basic and diluted		44,756,201		13,951,283		37,654,521		11,743,062

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30		
	 2021	2020	
Operating activities			
Net loss	\$ (4,926,265) \$	(3,868,074)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation, amortization and impairment	9,591	8,466	
Equity-based compensation expense	282,835	71,314	
Shares issued for services	—	25,000	
Change in fair value of warrant liability	3,868	(220,435)	
Changes in operating assets and liabilities:			
Grants receivable	(938,923)	(1,834,439)	
Prepaid expenses and other current assets	417,662	617,709	
Accounts payable	(577,877)	(741,018)	
Accrued expenses and other current liabilities	(168,461)	298,369	
Deferred revenue	 	(541,701)	
Net cash used in operating activities	(5,897,570)	(6,184,809)	
Financing activities			
Proceeds from issuance of equity securities, net	26,850,022	9,592,325	
Proceeds from warrants exercised for cash	1,485,351	578,714	
Payments on note payable	 (477,028)	(502,332)	
Net cash provided by financing activities	27,858,345	9,668,707	
Net increase in cash, cash equivalents and restricted cash	21,960,775	3,483,898	
Cash, cash equivalents and restricted cash at beginning of period	11,118,614	3,738,900	
Cash, cash equivalents and restricted cash at end of period	\$ 33,079,389 \$	7,222,798	
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 1,468 \$	4,275	
Non-cash investing and financing activities:			
Accrued issuance costs for public offering	\$ \$	125,159	

See accompanying notes to condensed consolidated financial statements.

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

	Common	Common Stock Preferred Stock		Additional	Total Stockholders'		
	Shares	Amount	Shares	Amount		Accumulated Deficit	Equity (Deficit)
Balance at December 31, 2019	4,511,174	\$ 451		_	\$22,657,103	\$(12,076,700)	\$ 10,580,854
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)
Balance at March 31, 2020	13,645,677	1,364	468,694	47	32,161,718	(14,160,516)	18,002,613
Warrants exercised for cash, net	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)
Balance at June 30, 2020	14,638,008	1,463			32,798,285	(15,944,774)	16,854,974
Balance at December 31, 2020	23,808,546	2,381			41,585,761	(19,428,954)	22,159,188
Issuance of equity securities, net	19,627,215	1,963			26,848,058		26,850,021
Warrants exercised for cash, net	1,298,567	129			1,485,222	_	1,485,351
Equity-based compensation expense	_	_	_	_	135,379	_	135,379
Net loss		—	—	—		(1,851,896)	(1,851,896)
Balance at March 31, 2021	44,734,328	\$ 4,473		_	\$70,054,420	\$(21,280,850)	\$ 48,778,043
Equity-based compensation expense	38,278	4			147,452		147,456
Equity-based services expense	6,188	_		—	—	—	—
Net loss						(3,074,369)	(3,074,369)
Balance at June 30, 2021	44,778,794	4,477			70,201,872	(24,355,219)	45,851,130

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 that 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.

#### **Risks Related to Covid-19 Pandemic**

The outbreak of COVID-19 has spread worldwide and has had a major impact on the United States and global economies and may in the future affect the Company's operations and those of third parties on which the Company relies. While the potential economic and operational impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the future 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 continues to be highly uncertain and subject to change and the Company does not yet know the full extent of potential delays or impacts on its business. 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.

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

#### **Basis of Presentation**

The accompanying unaudited 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").

#### **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, 2020 included elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2021. 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 June 30, 2021 and the results of operations for the three and six months ended June 30, 2021 and 2020. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2020 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.

#### 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 six months ended June 30, 2021 and 2020.

#### 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 six months ended June 30, 2021 or June 30, 2020, respectively.

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

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

#### Warrants

The Company determines whether 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. For warrants classified as equity contracts, the Company allocates the transaction proceeds to the warrants and any other free-standing instruments issued in the transaction based on an allowable allocation method.

#### **Clinical Trial Accruals**

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

#### Grants Receivable and Revenue Recognition

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

#### **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 9,520,698 and 9,606,690 shares as of June 30, 2021 and 2020, 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 June 30, 2021 and December 31, 2020, 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 December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740). The guidance eliminates certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. This guidance also includes guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for annual and interim periods in fiscal years beginning after December 15, 2020. The adoption of ASU 2019-12 in the first quarter of 2021 did not have a material impact on the Company's condensed consolidated financial statements.

#### NOTE 3. 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 \$4.8 million and \$3.9 million as of June 30, 2021 and December 31, 2020, respectively.

## NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at June 30, 2021 and December 31, 2020 consisted of the following:

	June	e 30, 2021	Decen	nber 31, 2020
Prepaid clinical trial expenses	\$	173,645	\$	
Prepaid insurance		117,306		684,268
Other prepaid and current assets		141,551		137,782
Total prepaid expenses and other current assets	\$	432,502	\$	822,050

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 was approximately \$0.9 million bearing interest at a rate of 2.49% and 4.61%, respectively. The note payable balances, which were included within Current Liabilities on the Condensed Consolidated Balance Sheets, were \$0 million and \$0.5 million at June 30, 2021 and December 31, 2020, respectively.

## NOTE 5. COMMITMENTS AND CONTINGENCIES

## License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which, the Company acquired an exclusive license to an epigenetic enzyme lysine specific demethylase 1 ("LSD1"). 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, further modified to \$16.1 million, to fund the development of an LSD1 inhibitor. This is a 3-year grant award which originally expired on May 31, 2019. The grant now expires on November 30, 2021 with extensions available.

The Company will retain ownership over any intellectual property developed under the contract ("Project Result"). With respect to noncommercial 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 June 30, 2021, the Company has expended all allowable funds under the grant.

At June 30, 2021 and December 31, 2020, the Company had grants receivable of \$4.8 million and \$3.9 million, respectively, related to the CPRIT contract.

## NOTE 6. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Significant unobservable inputs including Salarius' own assumptions in determining fair value.

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

The following table sets forth a summary of changes in the fair value of Level 3 liabilities, the warrants issued in connection with the Company's merger with Flex Pharma in 2019, which are measured at fair value on a recurring basis for the three and six months ended June 30, 2021:

Description	Balance at December 31, 2020		Change in Fair Value	Balance at June 30, 2021		
Warrant liability	\$	59,211	\$ 3,868	\$	63,079	

#### NOTE 7. STOCKHOLDERS' EQUITY

## 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 2020 Offering"). The February 2020 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 and exercise price of \$1.15 per share. A total of 8,353,480 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 exercise price of the warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features.

As discussed above, in connection with the February 2020 Offering, the Company issued five-year warrants to purchase one share of common stock at an exercise price of \$1.15 per share (each a "warrant"). On December 11, 2020, the Company entered into warrant exercise inducement offer letters ("Inducement Letters") with certain holders of 3,964,065 Warrants (collectively, the "Exercising Holders") pursuant to which such holders agreed to exercise on December 11, 2020 for cash, their Warrants to purchase 3,964,065 shares of Common Stock in exchange for the Company's agreement to (i) lower the exercise price of the Warrants held by the Exercising Holders to \$0.90 and (ii) issue new warrants (the "Inducement Warrants") to purchase up to 3,964,065 shares of Common Stock. Each Inducement Warrant is exercisable at a price per share of \$1.182 and expires on June 11, 2026.

On August 3, 2020, the Company completed a public offering of 5,130,390 shares of its common stock at a price to the public of \$1.20 per share. Total gross proceeds from the offering were approximately \$6.2 million, prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius.

On February 5, 2021, the Company entered into an At the Market Offering Agreement with Ladenburg Thalmann & Co. Inc. Under this agreement the Company is able to issue and sell, from time to time, shares of its common stock. On February 5, 2021 and July 2, 2021, the Company filed prospectus supplements with the SEC to register the offering and sale of Common Stock having an aggregate offering price of up to \$6.3 million and \$25.0 million, respectively. During the six months ended June 30, 2021, the Company issued 2,820,493 shares under the Sales Agreement for gross proceeds of \$6.3 million.

On March 8, 2021, the Company completed a public offering of 16,806,722 shares of its common stock at a price to the public of \$1.3685 per share. Total gross proceeds from the offering were approximately \$23.0 million prior to deducting underwriting discounts and commissions and offering expenses payable by Salarius.

## Warrants Exercised for Cash

During the six months ended June 30, 2021, the Company issued 1,298,567 common shares as a result of warrant exercises, and received cash proceeds of approximately \$1.5 million. As of June 30, 2021, 7,747,587 of warrants were still outstanding.

## **Right to Warrants**

On January 3, 2019, Flex Pharma, Private Salarius and Merger Sub entered into the Merger Agreement. Pursuant to the Merger Agreement, 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 were issued on July 1, 2021 and are exercisable in the aggregate, into 142,711 shares of the Company's common stock with a 5-year term from January 20, 2020, at 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:

	June 30, 2021	December 31, 2020
Discount rate	0.56%	0.27%
Expected life (years)	3.56 years	4.06 years
Expected volatility	130.87%	130.56%
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 \$0.5 million of the \$1.0 million success fee payable to Wedbush at the closing of the merger. The remaining \$0.5 million success fee was paid in cash. These warrants have an exercise price of \$18.90 and a 5-year term. As of June 30, 2021, all warrants issued to Wedbush were outstanding.

## NOTE 8. EQUITY-BASED COMPENSATION

#### **Equity Incentive Plans**

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). 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 June 30, 2021. 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 June 30, 2021, there were 1,037,190 shares remaining available for the grant of stock awards under the 2015 Plan.

During the six-month periods ended June 30, 2021 and 2020, the Company awarded 68,500 and 182,000, respectively, stock options to its employees and directors, pursuant to the plan described above. Stock options

generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants awarded during each of the six month periods ended June 30, 2021 and 2020 was \$0.1 million, which has been estimated with the following assumptions on the grant date.

	3/10/2021	6/16/2021	3/23/2020
Risk-free interest rate	1.00 %	1.09 %	0.48 %
Volatility	133.35 %	131.06 %	113.17 %
Expected life (years)	6.00	6.00	5.80
Expected dividend yield	0 %	0 %	0 %

The following table summarizes stock option activity for employees and non-employees for the six months ended June 30, 2021 and 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	182,000	0.61		
Exercised	—			
Forfeited	(26,000)	—		
Expired	_			
Outstanding at June 30, 2020	322,233	\$17.59	7.85	
Exercisable at June 30, 2020	84,711	\$59.61	3.00	\$—
Outstanding at December 31, 2020	1,563,972	\$2.78	9.47	\$175,770
Granted	68,500	\$1.13-\$1.49		
Exercised				
Forfeited	(45,000)			
Expired	—			
Outstanding at June 30, 2021	1,587,472	\$2.77	8.99	\$307,100
Exercisable at June 30, 2021	156,519	\$17.64	6.90	\$33,750

As of June 30, 2021 and 2020, there was approximately \$1.1 million and \$0.4 million of total unrecognized compensation cost related to unvested stock options. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.7 years.

## NOTE 9. SUBSEQUENT EVENTS

On July 12, 2021, the Small Business Administration (SBA) has authorized full Forgiveness of \$0.2 million for the Company's Paycheck Protection Program (PPP) Loan. The Company had previously recognized this as government grants and other income during the six months ended June 30, 2020.

## 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, 2020, filed with the SEC on March 18, 2021. 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, 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 that 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.

In 2011, Salarius licensed SP-2577 and related compounds from the University of Utah Research Foundation. 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. To effectively develop SP-2577, we are pursuing a speed-to-market and market expansion strategy.

As part of our speed-to-market strategy, we are initially focused on developing SP-2577 for the treatment of sarcomas with high unmet needs. We are investigating SP-2577 for the treatment of several advanced sarcoma subtypes, including Ewing sarcoma, myxoid liposarcoma, and other sarcomas that share similar biology, i.e. FET-rearranged sarcomas. The described sarcomas are all driven by a chromosomal translocation involving a FET-gene family member (EWS, FUS, or TAF15). The translocation results in an FET-rearranged fusion oncoprotein. SP-2577's target, LSD1, has been shown to associate with FET-rearranged fusion oncoproteins to help promote tumor growth.

We believe SP-2577 disrupts LSD1 from associating with FET-rearranged fusion oncoprotein and therefore leads to inhibition of the fusion oncoprotein's cancer promoting activity. As a result, SP-2577 has the potential to treat FET-rearranged sarcomas by reversing cancer promoting gene expression and thereby possibly preventing tumor growth and causing cancer cell death. Preclinical studies of SP-2577 in several FET-rearranged sarcoma cell lines including Ewing sarcoma, myxoid liposarcoma, clear cell sarcoma, and desmoplastic small round cell tumors demonstrated that SP-2577 was effective in inhibiting cell proliferation and viability. Additionally, in certain Ewing sarcoma animal models, SP-2577 showed a significant tumor reduction as well as a significant survival benefit compared to untreated animals. Our ongoing Phase 1/2 clinical trial was designed as a single agent dose escalation followed by a dose expansion study in Ewing sarcoma. However, given the described preclinical data in other FET-rearranged sarcomas and clinical data in FET-rearranged sarcomas. The amended ongoing dose expansion portion of the trial is studying SP-2577 in combination with a common chemotherapeutic regimen, topotecan and cyclophosphamide ("TC") in Ewing sarcoma patients and single agent SP-2577 in myxoid liposarcoma and other FET-rearranged sarcoma patients and up to 30 relapsed or refractory Ewing sarcoma patients, the trial will assess the safety and tolerability of SP-2577 and TC and study preliminary efficacy of the regimen. In myxoid liposarcoma and other FET-rearranged sarcoma patients, the trial is studying SP-2577 safety, tolerability, and preliminary efficacy.



As LSD1 can interact with over 60 regulatory proteins other than FET-fusion oncoproteins, we believe that LSD1 may also play a critical role in progression of various other cancer types. Preliminary efficacy data from our Phase 1/2 AST trial supports this notion and work is ongoing to identify large market solid tumor indications with the highest potential for SP-2577 success. Continued progress in this area will support the market expansion portion of our strategy.

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

Recent data from "LSD1 Ablation Stimulates Anti-tumor Immunity and Enables Checkpoint Blockade" by W. Sheng, et al. and "Inhibition of Histone Lysine-specific Demethylase 1 Elicits Breast Tumor Immunity and Enhances Antitumor Efficacy of Immune Checkpoint Blockade" by Y. Qin, et al. suggests that LSD1 plays a role in tumor immune activity and can sensitize tumors to checkpoint inhibitors. These works have sparked interest in combining LSD1 inhibitors with checkpoint inhibitors. 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 \$24.4 million as of June 30, 2021. 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, 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 June 30, 2021, the Cancer Prevention and Research Institution of Texas ("CPRIT") fund matching requirements had been fully met and we have expended all allowable funds under the grant. Our June 30, 2021 balance sheet reflects a receivable due from CPRIT of approximately \$4.8 million.

Based on our current operating plan, we believe that our \$33.1 million in cash and cash equivalents on hand as of June 30, 2021, and the collection of the CPRIT receivable are sufficient to fund our anticipated operating and capital requirements through the completion of our current clinical trials in 2022 and beyond, 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 2, 2021, the Company filed a prospectus supplement with the SEC to register the offering and sale of our common stock pursuant to the terms of that certain At the Market Offering Agreement (the "Sales Agreement") between the Company and Ladenburg Thalmann & Co. Inc. ("Ladenburg"), dated as of on February 5, 2021, having an aggregate offering price of up to \$25.0 million (the "Additional Shares"). We had previously filed a prospectus supplement with the SEC registering the offering and sale of our common stock under the Sales Agreement having an aggregate offering price of up to \$6.3 million (together with the Additional Shares, the "ATM Shares"). Under the Sales Agreement the Company is able to issue and sell, from time to time, shares of its common stock with Ladenburg acting as an agent for such sales. Sales of the ATM Shares may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including, without limitation, sales made directly on or through the NASDAQ Capital Market. During the six months ended June 30, 2021, we issued 2,820,493 shares under the Sales Agreement for net proceeds of \$6.0 million.

On June 15, 2021, we announced the initiation of a clinical trial to investigate seclidemstat in combination with azacitidine for the treatment of Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML). The investigator-initiated Phase 1/2 trial is being led by the Department of Leukemia at The University of Texas MD Anderson Cancer Center. We expect preliminary data from the trial by mid - 2022.

In June 2021, we completed the dose-escalation stage of our Advanced Solid Tumor trial. The trial provided safety and pharmacokinetic data across several advanced tumor types. In addition, encouraging preliminary seclidemstat efficacy data in treated FET-rearranged sarcoma patients supported the expansion of the Phase 2 portion of our Ewing sarcoma trial to enroll additional select sarcoma patients, including myxoid liposarcoma patient and patients with other FET-rearranged sarcomas, thereby increasing seclidemstat's addressable patient population. Upon completing dose escalation, the AST trial was closed to enrollment and work is ongoing to identify large market solid tumor indications with the highest potential for SP-2577 success.

Effective June 17, 2021, we terminated that certain Exclusive Pharmaceutical Sublicense Agreement between the Company and HLB Life Sciences ("HLBLS"), a South Korean company, dated November 25, 2016 (the "HLBLS Agreement"). Pursuant to the original terms of the HLBLS Agreement, HLBLS had sublicensed the patent and technology rights related to SP-2577 mesylate salt in South Korea, and for the right to develop, produce, manufacture, use and sell the drug in South Korea. As of the termination date, HLB no longer has rights to develop, produce, manufacture, use and sell our product.

### 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. 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 may encounter delays in enrolling new patients due to concerns or healthcare resource constraints because 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. 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, we have worked to adapt to the unexpected and challenging circumstances resulting from the COVID-19 pandemic. 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.



## **Results of Operations**

## Three Months Ended June 30, 2021 Compared to the Three Months Ended June 30, 2020

The following table sets forth the condensed consolidated results of our operations for the three months ended June 30, 2021 compared to the three months ended June 30, 2020.

	Three months ended June 30			Effect on Net Loss(a)			
		2021		2020		\$	%
Grant revenue	\$	571,387	\$	1,243,310	\$	(671,923)	(54)%
Research and development expenses		(2,096,302)		(1,443,322)		(652,980)	(45)%
General and administrative expenses		(1,591,905)		(1,700,942)		109,037	6 %
Change in fair value of warrant liability		42,186		(62,635)		104,821	(167)%
Government grants and other income				179,027		(179,027)	(100)%
Interest (expense) income		265		304		(39)	13 %
Net loss	\$	(3,074,369)	\$	(1,784,258)	\$	(1,290,111)	(72)%

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

#### **Grant Revenue**

Grant revenue, which was derived solely from the CPRIT grant, decreased in the current period resulting from the completion of CPRIT available funding under the grant. Partial expenses incurred during the three months ended June 30, 2021 were not recognized as revenue and grants receivable since we reached the maximum amount of the eligible spending that can be reimbursed from CPRIT.

## **Research and Development Expenses**

Research and development expenses increased during the current period compared to the same period in 2020 resulting from significantly higher personnel and, clinical trial costs related to the increase in patient enrollment and higher laboratory costs resulting from increased non clinical efforts which more than offset lower professional fee expenses.

## General and Administrative Expenses

General and administrative expenses decreased slightly during the current period compared to the same period a year ago resulting from lower legal and overall personnel cost (severance costs in 2020 that did not repeat in the current period) and more than offset an increase in professional fees.



## Six Months Ended June 30, 2021 Compared to the Six Months Ended June 30, 2020

The following table sets forth the condensed consolidated results of our operations for the six months ended June 30, 2021 compared to the six months ended June 30, 2020.

	Six months ended June 30			Effect on Net Loss(a)			
		2021		2020		\$	%
Grant revenue	\$	1,840,216	\$	2,376,140	\$	(535,924)	(23)%
Research and development expenses		(3,836,957)		(3,086,693)		(750,264)	24 %
General and administrative expenses		(2,924,674)		(3,559,959)		635,285	(18)%
Change in fair value of warrant liability		(3,868)		220,435		(224,303)	(102)%
Government grants and other income		_		179,027		(179,027)	(100)%
Interest (expense) income		(982)		2,976		(3,958)	(133)%
Net loss	\$	(4,926,265)	\$	(3,868,074)	\$	(1,058,191)	27 %

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

#### **Grant Revenue**

Grant revenue, which was derived solely from the CPRIT grant, decreased in the current period resulting from the completion of CPRIT available funding under the grant. Partial expenses incurred during the six months ended June 30, 2021 were not recognized as revenue and grants receivable since we reached the maximum amount of the eligible spending that can be reimbursed from CPRIT.

#### **Research and Development Expenses**

Research and development expenses increased during the current period compared to the same period in 2020 resulting from significantly higher personnel related expenses, higher clinical trial costs related to the increase in patient enrollment, and higher laboratory costs resulting from increased non clinical efforts which more than offset lower professional fee expenses.

#### General and Administrative Expenses

General and administrative expenses decreased significantly during the current period compared to the same period a year ago resulting from lower legal and personnel related costs (severance costs incurred in 2020 that did not recur in the current year) and lower travel costs which more than offset a slight increase in insurance related expenses.

## 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 secured capital from the sale of equity and grant revenue.

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 research and development and manufacturing activities.

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.

We believe that, based on our current operating plan, our current unrestricted cash and cash and cash equivalent balances will be sufficient to fund our operations through the completion of our current clinical trials in 2022 and beyond.

As of June 30, 2021, we had \$36.8 million of working capital and our cash and cash equivalents totaled \$33.1 million, which were held in bank deposit accounts and a money market account. Our cash and cash equivalents balance increased during the six months ended June 30, 2021, primarily due to sales of our common stock in our public offering which closed on March 8, 2021.

#### **Cash Flows**

	Six months ended June 30,				
	 2021		2020		
Net cash (used in) provided by in:					
Operating activities	\$ (5,897,570)	\$	(6,184,809)		
Financing activities	27,858,345		9,668,707		
Net increase in cash and cash equivalents	\$ 21,960,775	\$	3,483,898		

#### **Operating Activities**

Net cash used in operating activities was \$5.9 million in the current period, a decrease of approximately \$0.29 million from the same period a year ago.

## **Financing Activities**

Net cash provided by financing activities for the six months ended June 30, 2021 was \$27.9 million, compared to \$9.7 million for the same period of the year 2020. The increase resulted from the Company's completion of common stock sales in February and a public offering in March 2021 with total net proceeds of approximately \$27.0 million, and the receipt of approximately \$1.5 million from the exercise of warrants during the six months ended June 30, 2021.

## **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 18, 2021.

Readers should refer to our Annual Report on Form10-K filed with SEC on March 18, 2021, 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 the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer) concluded that 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 as of the end of the period covered by this Quarterly Report

## **Changes in Internal Control over Financial Reporting**

During the six months ended June 30, 2021, 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, 2020, filed with the SEC on March 18, 2021, 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 From 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 18, 2021 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 and our manufacturing capabilities during the six months ended June 30, 2021. Both our Ewing sarcoma clinical study and our Advanced Solid Tumor clinical study are

active. We plan to release clinical data from both studies, as previously disclosed, during 2021 and 2022. 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 2021 and beyond.

## Risks Related to Salarius' Financial Condition and Capital Requirements

#### 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 \$7.4 million for the year ended December 31, 2020, and we have incurred a net loss of \$3.1 and \$4.9 million for the three and six months ended June 30, 2021, 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 and funding our operations have been funded through sales of equity and funds 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. 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.



#### We rely on funding from CPRIT and failure to receive additional funds may harm our business.

During the course of the development of our product candidates, we have been funded through the sale of equity and the funding we received from the CPRIT grant. The CPRIT agreement was awarded in June 2016 and originally provided for a three-year grant award of up to \$18.7 million, further modified to \$16.1 million, to fund the development of the LSD-1 inhibitor. We have received \$11.3 million since inception of the grant. The term of the CPRIT agreement was extended through November 30, 2021. We currently have a \$4.8 million receivable due from CPRIT on our June 30, 2021 balance sheet. 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. 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.

#### **Risks Related to Our Common Stock**

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

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

For example, if at any time the bid price of our common stock closes at below \$1.00 per share for more than 30 consecutive trading days, we may be subject to delisting from the Nasdaq Capital Market. If we receive a delisting notice, we would have 180 calendar days to regain compliance (subject to any additional 180-day compliance period which may be available to us), which would mean having a bid price above the minimum of \$1.00 for at least 10 consecutive days in the 180-day period. During this 180-day period, we would anticipate reviewing our options to regain compliance with the minimum bid requirements, including conducting a reverse stock split. To the extent that we are unable to resolve any listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock. On July 29, 2021, the closing price of our common stock was \$0.85 per share.

## Item 6. Exhibits

Exhibit number	Description of Document
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*	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.
101.0	The following materials from Salarius Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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 Condensed Consolidated Financial Statements.

<sup>\*</sup> 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: August 5, 2021

## Certification Pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) 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 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)

August 5, 2021

## Certification Pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) 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 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)

August 5, 2021

## 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 June 30, 2021 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.

/s/ David J. Arthur David J. Arthur August 5, 2021 President and Chief Executive Officer (Principal Executive Officer) /s/ Mark J. Rosenblum Mark J. Rosenblum Executive Vice President and Interim Chief Financial Officer August 5, 2021 (Principal Financial Officer and Principal Accounting Officer)