# **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, 2023

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

Commission File Number: 001-36812

# SALARIUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

46-5087339

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

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

(832)804-9144

exchange on which registered sdaq Stock Market LLC
sdaq Stock Market LLC
e Act of 1934 during the preceding ents for the past 90 days. Yes 🗵 No [o Rule 405 of Regulation S-T etc.). Yes 🗵 No [o Rule 405 of Regulation S-T etc.). Yes 🖾 No [o Rule 405 of Regulation S-T etc.). Yes [o Rule 405 of Regulation S-T etc.]. Employed The Exchange Act.  Emerging Growth Company [o Rule 405]  Emerging Growth Company [o Rule 405]  Emerging With any new or revised financial

# SALARIUS PHARMACEUTICALS, INC.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the Company's expectation regarding the exploration of strategic alternatives;
- the Company's planned strategy; including reducing its expenditures on research and development activities and taking other cost savings measures in connection with the decision to evaluate strategic alternatives;
- the Company's ability to continue as a going concern and its ability to obtain additional capital to support its operations beyond the fourth quarter of 2023;
- estimated costs associated with the Company's cost savings plan;
- the expected timing of implementing and completing the the Company's cost savings plan;
- the Company's ability to preserve capital while it continues to assess potential strategic alternatives;
- the expected timing for incurring costs associated with the cost savings plan;
- the Company's clinical trials, including expected costs, goals, timing and other expectations related thereto;
- the potential advantages of its lead compound, seclidemstat or SP-2577, as a treatment for Ewing sarcoma, and other cancers and its ability to improve the life of patients;
- the potential for seclidemstat to target the epigenetic dysregulation underlying Ewing sarcoma and advanced solid tumors;
- the future of the company's Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas;
- the potential advantages of protein degraders including the value of SP-3164 as a cancer treatment;
- the commercial or market opportunity and expansion for each therapeutic option, including the availability and value of a pediatric priority review voucher for in-clinic treatments and potential for accelerated approval;
- the Company's expectations as to revenue, cash flow, and expenses; and
- the Company's liquidity position, the expected insufficiency of such position to support anticipated operating and capital requirements;

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

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

- uncertainties about the exploration and evaluation of strategic alternatives, including that they may not result in a definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect our operating results, business or investor perceptions;
- potential adverse impacts resulting from our recent announcement regarding our board of directors' review of potential strategic alternatives for the Company;
- we may not be able to implement the cost savings plan as currently anticipated or within the timing currently anticipated;
- the impact of the workforce reduction on the Company's business:

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- the risk that the Company's cost saving initiatives may not be successful;
- unanticipated difficulties with preserving capital;
- unanticipated charges not currently contemplated that may occur as a result of the Company's cost savings plan;
- our ability to raise additional capital;
- the effectiveness and timeliness of our preclinical studies and possible future clinical trials, and the usefulness of the data;
- the adequacy of our capital to support our future operations
- fluctuations in our operating results;
- the success of current and future license and collaboration agreements;
- our dependence on contract research organizations, vendors and investigators;
- effects of competition and other developments affecting development of products;
- market acceptance of our product candidates;
- protection of intellectual property and avoiding intellectual property infringement;
- product liability; and
- other factors described in our filings with the SEC.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

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

# **PART I - FINANCIAL INFORMATION**

# Item 1. Financial Statements

# SALARIUS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	6/30/2023			12/31/2022
		(Unaudited)		(Audited)
Assets				
Current assets:				
Cash and cash equivalents	\$	11,541,443	\$	12,106,435
Grants receivable from CPRIT		130,000		1,610,490
Prepaid expenses and other current assets		284,807		803,373
Total current assets		11,956,250		14,520,298
Other assets		99,048		130,501
Total assets	\$	12,055,298	\$	14,650,799
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	2,287,243	\$	2,858,330
Accrued expenses and other current liabilities		1,354,253		1,407,861
Total liabilities		3,641,496		4,266,191
Commitments and contingencies (Note 5)				
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; 3,352,069 and 2,255,899 shares issued and outstanding at June 30, 2023 and December 31, 2022,				
respectively		335		225
Additional paid-in capital		81,436,696		74,189,531
Accumulated deficit		(73,023,229)		(63,805,148)
Total stockholders' equity		8,413,802		10,384,608
Total liabilities and stockholders' equity	\$	12,055,298	\$	14,650,799

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

**Three Months Ended Six Months Ended** June 30 June 30 2023 2023 2022 2022 Operating expenses: Research and development \$ 2,351,852 2,921,572 6,077,440 7,361,047 \$ General and administrative 1,619,543 1,836,395 3,314,618 3,514,149 Total operating expenses 3,971,395 4,757,967 9,392,058 10,875,196 Loss before other income (expense) (3,971,395)(4,757,967)(9,392,058)(10,875,196)Interest income, net and other 94,087 39,629 173,977 47,633 (3,877,308)(4,718,338)(9,218,081) (10,827,563)Loss from continuing operations \$ (3,877,308)\$ (4,718,338)\$ (9,218,081)\$ (10,827,563)**Net loss** Loss per common share — basic and diluted (1.43)(2.20)(3.45)(5.42)\$ Weighted-average number of common shares outstanding — 2,709,104 2,140,899 2,671,148 1,996,357 basic and diluted

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

Six Months Ended

	June 30			
		2023		2022
Operating activities				
Net loss	\$	(9,218,081)	\$	(10,827,563)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		3,338		3,340
Equity-based compensation expense		326,804		513,431
In-process research and development technology		_		1,987,900
Changes in operating assets and liabilities:				
Grants receivable		1,480,490		_
Prepaid expenses and other current assets		546,681		609,170
Accounts payable		(671,506)		245,959
Accrued expenses and other current liabilities		(53,608)		327,318
Net cash used in operating activities		(7,585,882)		(7,140,445)
Investing activities				
Purchase in-process research and development technology		_		(1,500,000)
Net cash used in investing activities		_		(1,500,000)
Financing activities				
Proceeds from issuance of equity securities, net		7,020,890		2,073,070
Net cash provided by financing activities		7,020,890		2,073,070
iver cash provided by financing activities		7,020,090		2,073,070
Net decrease in cash, cash equivalents and restricted cash		(564,992)		(6,567,375)
Cash, cash equivalents and restricted cash at beginning of period		12,106,435		29,214,380
Cash, cash equivalents and restricted cash at end of period	\$	11,541,443	\$	22,647,005
Supplemental disclosure of cash flow information:				
Non-cash investing and financing activities:				
Common stock issued for in-process research and development technology	\$		\$	487,900
Accrued issuance costs for issuance of equity securities	\$	100,419	\$	_

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

_	Common Stock Shares Amoun		:k	Additional Paid-In	Accumulated		Total Stockholders'
					Deficit		quity (Deficit)
Balance at December 31, 2021	1,809,593	\$	181	\$70,919,996	\$(32,197,192)	\$	38,722,985
Common stock issued for in-process research and development technology	40.000		4	487,896			487,900
Equity-based compensation expense	18,215		2	313,901			313.903
Net loss	10,213		_	313,301	(6,109,225)		(6,109,225)
Balance at March 31, 2022	1,867,808	\$	187	\$71,721,793	\$(38,306,417)	\$	33,415,563
Issuance of equity securities, net	373.577		37	1.987.339	_	_	1,987,376
Equity-based compensation expense	3,184		_	174,528	_		174,528
Issuance of equity securities for services	_		_	25,000	_		25,000
Net loss	_		_	_	(4,718,338)		(4,718,338)
Balance at June 30, 2022	2,244,569		224	73,908,660	(43,024,755)		30,884,129
-						_	
Balance at December 31, 2022	2,255,899	\$	225	\$74,189,531	\$(63,805,148)	\$	10,384,608
Issuance of equity securities, net	142,499		14	311,667	_		311,681
Equity-based compensation expense	69,899		7	203,338	_		203,345
Net loss					(5,340,773)		(5,340,773)
Balance at March 31, 2023	2,468,297	\$	246	\$74,704,536	\$(69,145,921)	\$	5,558,861
Issuance of equity securities, net	883,772		89	6,608,701	_		6,608,790
Equity-based compensation expense	_		_	123,459	_		123,459
Net loss	_		_	_	(3,877,308)		(3,877,308)
Balance at June 30, 2023	3,352,069	\$	335	\$ 81,436,696	\$ (73,023,229)	\$	8,413,802

# 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 Company is developing two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. The Company's technologies have the potential to work in both liquid and solid tumors. The Company's current pipeline consists of two small molecule drugs: 1) SP-3164, a targeted protein degrader, and 2) seclidemstat (SP-2577), a targeted protein inhibitor. The Company is located in Houston, Texas.

#### **Going Concern**

Salarius has no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Salarius will require substantial additional capital to fund its research and development expenses related to its pipeline including SP-3164 and seclidemstat. Based on Salarius' expected cash requirements, Salarius believes that there is substantial doubt that its existing cash and cash equivalents, will be sufficient to fund its operations through one year from the financial statements' issuance date. The Company may attempt 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.

#### 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").

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

#### **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, 2022 included elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2023. 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, 2023 and the results of operations for the three and six months ended June 30, 2023 and 2022. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2022 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.

#### 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, 2023 and 2022.

#### **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. Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

#### Warrants

The Company determines whether warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs with changes in fair value recorded in the 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**

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.

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

#### **Equity-Based Compensation**

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

The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options granted to employees and directors. 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. Restricted stock and restricted stock units granted to employees and directors are measured at fair value based upon the closing price of the Company's common stock on the grant date.

#### **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) rights entitling holders to receive warrants to purchase the Company's common shares, and (iv) restricted stock units which have been excluded from the computation of diluted loss per share, was approximately 11,550,477 and 712,311 shares as of June 30, 2023 and 2022, 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.

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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, 2023 and December 31, 2022, 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.

#### Acquisition and Strategic Collaboration Agreement - DeuteRx

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

#### **Recently Adopted Accounting Standard**

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 825), 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 was effective for the Company on January 1, 2023. The adoption of this standard did not have a material impact to this Company's consolidated financial statements.

### NOTE 3. GRANT RECEIVABLE FROM CPRIT

Grants receivable represents qualifying costs incurred where there is reasonable assurance that conditions of the grant have been met but the corresponding funds have not been received as of the reporting date. Grants receivable balances are \$0.1 million and \$1.6 million at June 30, 2023 and December 31, 2022. During the three and six months ended June 30, 2023, the Company received \$0 million and \$1.5 million from CPRIT, respectively.

# NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at June 30, 2023 and December 31, 2022 consisted of the following:

	June 30, 2023			ember 31, 2022
Prepaid clinical trial expenses	\$	_	\$	11,185
Prepaid insurance		110,409		624,612
Other prepaid and current assets		174,398		167,576
Total prepaid expenses and other current assets	\$	284,807	\$	803,373

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

#### NOTE 5. COMMITMENTS AND CONTINGENCIES

#### License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which the Company acquired 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 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 up to \$18.7 million further modified to \$16.1 million to fund development of LSD 1 inhibitor. This is a 3-year grant award that originally expired on May 31, 2019. The Company applied for a no- cost extension through November 30, 2023. Since inception, the Company has received approximately \$16 million under the grant, the remaining \$0.1 million is included on the balance sheet at June 30, 2023.

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

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

#### **Lease Agreement**

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

### **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 guoted 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.

## **NOTE 7. STOCKHOLDERS' EQUITY**

#### **Common Stock - Issuances**

During the six months ended June 30, 2023, the Company sold 696,271 ATM shares under the Sales Agreement, with gross proceeds of \$1.7 million.

On May 11, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an accredited investor (the "Investor"), pursuant to which the Company agreed to issue and sell to the Investor in a private placement (the "Offering") (i) 330,000 shares (the "Shares") of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 3,306,364 shares of Common Stock, (iii) Series A-1 warrants (the "Series A-1 Warrants") to purchase up to 3,636,364 shares of Common Stock and (iv) Series A-2 warrants (the "Series A-2 Warrants") and together with the Series A-1 Warrants, the "Common Stock Warrants," and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 3,636,364 shares of Common Stock, at a purchase price of (a) \$1.65 per Share and accompanying Common Stock Warrants and (b) \$1.6499 per Pre-Funded Warrant and accompanying Common Stock Warrants. The aggregate gross proceeds from the Offering were approximately \$6.0 million, exclusive of placement agent fees and expenses and other offering expenses. The closing of the Offering occurred on May 16, 2023.

On January 12, 2022, the Company issued 40,000 shares of the Company's common stock, valued at \$0.5 million to purchase in-process research and development technology related to SP-3164, please refer to NOTE 2 for further discussion.

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

#### **Warrants Exercisable for Cash**

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

The Company's Series A-1 Warrants are exercisable for a period of five and one-half (5.5) years from the issuance date at an exercise price of \$1.40 per share. Series A-2 Warrants are exercisable for a period of eighteen (18) months from the issuance date at an exercise price of \$1.40 per share. Each Pre-Funded Warrant was sold in lieu

of shares of Common Stock, are exercisable immediately upon issuance, have an exercise price of \$0.0001 per share and expire when exercised in full.

In connection with the above mentioned Offering, the Company issued warrants to its exclusive placement agency H.C Wainwright & Co., LLC to purchase up to 254,454 shares of common stock at an exercise price per share of \$2.0625 and a term of five and one-half (5.5) years.

As of June 30, 2023 and 2022, approximately 11,431,149 and 597,512 warrants remain outstanding.

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

#### **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"). 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, 2023, there were approximately 55,365 shares remaining available for the grant of option awards under the 2015 Plan.

During the six months ended June 30, 2023, the Company awarded 12,220 restricted stock units to its employees and 36,640 restricted stock awards to its officers and directors, pursuant to the plan described above. Both the restricted stock units and restricted stock awards are valued at the closing price \$1.57 of the Company's common stock on the grant date, and generally vest over one to four years. Total fair value of the restricted stock awards and restricted stock units awarded during the six - month period ended June 30, 2023 is \$76,679.

During the six-month periods ended June 30, 2023 and 2022, the Company awarded 0 and 51,360 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 the six - month period ended June 30, 2022 was \$0.5 million, which has been estimated with the following assumptions on the grant date.

	Six Months Ended June 30 2022
Risk-free interest rate	1.62%-1.70%
Volatility	125.19% 126.42%
Expected life (years)	5.00-6.00
Expected dividend yield	0%

The following table summarizes stock option activity for employees and non-employees for the six months ended June 30, 2023 and 2022:

Shares	E	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)		Aggregate Intrinsic Value
63,919	\$	68.75	8.50	\$	_
51,360	\$	12.00			
_					
(480)					
_					
114,799	\$	43.50	8.70	\$	_
34,276	\$	103.25	7.81	\$	_
107,128	\$	23.67	8.29	\$	_
_					
_					
_					
_					
107,128	\$	23.67	7.79	\$	_
59,870	\$	28.30	7.60	\$	_
	63,919 51,360 — (480) — 114,799 34,276 — — — — — — — — —	63,919 \$ 51,360 \$  — (480) — 114,799 \$ 34,276 \$  107,128 \$ — — 107,128 \$	Shares         Average Exercise Price           63,919         \$ 68.75           51,360         \$ 12.00           —         (480)           —         43.50           34,276         \$ 103.25           107,128         \$ 23.67           —         —           —         —           107,128         \$ 23.67	Shares         Weighted-Average Exercise Price         Remaining Contractual Term (in years)           63,919         \$ 68.75         8.50           51,360         \$ 12.00         \$ 2           —         (480)         \$ 43.50         8.70           34,276         \$ 103.25         7.81           107,128         \$ 23.67         8.29           —         —         —           107,128         \$ 23.67         7.79	Shares         Weighted-Average Exercise Price         Average Remaining Contractual Term (in years)           63,919         \$ 68.75         8.50         \$           51,360         \$ 12.00         \$            (480)             114,799         \$ 43.50         8.70         \$           34,276         \$ 103.25         7.81         \$           107,128         \$ 23.67         8.29         \$                 107,128         \$ 23.67         7.79         \$

As of June 30, 2023 and 2022, there was approximately \$0.6 million and \$1.2 million, respectively, 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 1.7 years.

#### **NOTE 10 SUBSEQUENT EVENTS**

#### **Strategic Alternatives**

On August 8, 2023 the Company announced it had retained Canaccord Genuity, LLC to lead a comprehensive review of strategic alternatives focusing on maximizing shareholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing, or other strategic transactions involving the Company. However, there is no set timetable for this process and there can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. If the Company is unable to complete a transaction, it may be necessary to seek other alternatives for restructuring and resolving its liabilities, including an orderly wind-down. Salarius does not expect to disclose developments with respect to this process unless and until the evaluation of strategic alternatives has been completed or the Board of Directors has concluded that disclosure is appropriate or legally required.

In connection with the evaluation of strategic alternatives and in order to extend its resources, Salarius is implementing a cost-savings plan that includes a reduction in workforce by over 50% of its positions, with remaining employees focusing primarily on limited drug development activities, completing the US Food and Drug Administration process to determine the clinical trial registration requirements for the seclidemstat Ewing sarcoma program and supporting the exploration of strategic alternatives

## FDA Clearance of SP-3164 Investigational New Drug (IND) Application

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On July 11, 2023 the Company announced that the FDA had completed its safety review of the Company's IND application and concluded that the Company may proceed with clinical investigations for Non-Hodgkin's lymphoma.

#### 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, 2022, filed with the SEC on March 27, 2023. 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, 2022, 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.

#### **Recent Developments**

On August 8, 2023, we announced that we retained Canaccord Genuity, LLC to lead a comprehensive review of strategic alternatives focusing on maximizing shareholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing, or other strategic transactions involving our company. However, there is no set timetable for this process and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. If we are unable to complete a transaction, it may be necessary to seek other alternatives for restructuring and resolving our liabilities, including an orderly wind-down. We do not expect to disclose developments with respect to this process unless and until the evaluation of strategic alternatives has been completed or our Board of Directors has concluded that disclosure is appropriate or legally required.

In connection with the evaluation of strategic alternatives and in order to extend our resources, we are implementing a cost-savings plan that includes a reduction in workforce by over 50% of our positions, with remaining employees focusing primarily on limited drug development activities, completing the US Food and Drug Administration process to determine the clinical trial registration requirements for the seclidemstat Ewing sarcoma program and supporting the exploration of strategic alternatives

#### Overview

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

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 \$73.0 million as of June 30, 2023. 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. As of June 30, 2023, we had cash and cash equivalents of \$11.5 million.

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 believe that there is presently insufficient funding available to allow us to continue our current and planned clinical programs for a period exceeding 12 months from the date of this filing with the SEC.

The lack of revenue from product sales to date and recurring losses from operations since our inception raise substantial doubt as to our ability to continue as a going concern. We will continue to require substantial additional capital to continue our clinical development activities will likely need such additional capital sooner than 12 months and will need to raise substantial additional capital in the future to continue to fund our operations. The amount and

timing of our future funding requirements will depend on many factors, including the results of our evaluation of strategic alternatives, the pace and results of our development, regulatory approvals and authorizations, commercialization efforts and market conditions. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop and commercialize our product candidates.

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

## **Program Development**

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

#### SP-3164 - Targeted Protein Degradation

SP-3164 is a next-generation cereblon-binding molecular glue. Molecular glues are small molecules that commandeer the body's normal protein degradation processes by causing proteins to stick to one another thereby inducing selective degradation of cancer-causing proteins. Derived from avadomide, SP-3164 is engineered using DECS (deuterium-enabled chiral switching), a process that replaces hydrogen atoms with deuterium to stabilize the molecule's active enantiomer, resulting in a novel molecular entity with the potential for increased efficacy and improved safety compared to the 1st generation compound. SP-3164 degrades transcription factors Ikaros (IKZF1) and Aiolos (IKZF3), resulting in both direct anti-cancer activity and immune-modulating properties. SP-3164 has potential to treat both hematologic and solid tumors. We have presented preclinical data of SP-3164 in hematological cancers at several scientific conferences highlighting its activity and differentiation. On July 11, 2023 we announced that the FDA had cleared our IND application to treat relapsed/refractory non-Hodgkin lymphoma patients with SP-3164.

#### Seclidemstat - Targeted Protein Inhibition

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

SP-2577 is being developed for both solid and liquid tumors. Our lead indication for SP-2577 is a devastating bone and soft-tissue cancer called Ewing sarcoma, which has a median age of diagnosis of 15. We are currently in a Phase 1/2 trial to treat relapsed/refractory Ewing sarcoma patients in combination with topotecan and cyclophosphamide. In addition, as part of our market expansion strategy, in 2021 an Investigator Initiated Trial with the MD Anderson Cancer Center was initiated to study SP-2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). MDS and CMML can progress into Acute Myeloid Leukemia (AML), which the American Cancer Society estimates there were almost 20,000 new cases of AML in the US alone in 2020.

#### **Results of Operations**

#### Three months ended June 30, 2023 Compared to the Three months ended June 30, 2022

The following table sets forth the condensed consolidated results of our operations for the three months ended June 30, 2023 compared to June 30, 2022.

	Three months	\$ Change		
	2023	2022		
Research and development expenses	\$ 2,351,852	\$ 2,921,572	\$	(569,720)
General and administrative expenses	1,619,543	1,836,395		(216,852)
Interest income, net and other	94,087	39,629		54,458
Net loss	\$ (3,877,308)	\$ (4,718,338)	\$	841,030

#### Research and Development Expenses

Research and development expenses decreased during the three months ended June 30, 2023 compared to the same period in 2022 primarily due to lower spending on SP-2577 offset by higher spending in SP-3164 in 2023.

We expect total research and development expenses and research and development expense for each of our research and development projects to decrease in the remainder of 2023 as compared to the prior year and into 2024 as compared to 2023 as we evaluate the development strategy for our product candidates, and explore and evaluate strategic alternatives.

	<u>SP-2577</u>				<u>SP-3164</u>				
Research and development costs by candidates				Three month	s end	ed June 30,			
and by categories:		2023		2022		2023		2022	
Outsourced research and development costs	\$	544,937	\$	1,380,125	\$	773,463	\$	341,626	
Employee-related costs		515,242		532,017		52,092		44,707	
Manufacturing and laboratory costs		14,753		189,875		451,365		433,222	
Total research and development costs	\$	1,074,932	\$	2,102,017	\$	1,276,920	\$	819,555	

# General and Administrative Expenses

General and administrative expenses were \$1.6 million during the three months ended June 30, 2023, compared to \$1.8 million for the three months ended June 30, 2022, resulting from lower proxy service expense and overall compensation and benefit costs in current year.

Six Months Ended June 30, 2023Compared to the Six Months Ended June 30, 2022

The following table sets forth the condensed consolidated results of our operations for the six months ended June 30, 2023 compared to June 30, 2022.

	Six months e	\$ Change	
	2023	2022	
Research and development expenses	\$ 6,077,440	\$ 7,361,047	\$ (1,283,607)
General and administrative expenses	3,314,618	3,514,149	(199,531)
Interest income, net and other	173,977	47,633	126,344
Net loss	\$ 9,218,081	\$ 10,827,563	\$ (1,609,482)

### Research and Development Expenses

Research and development expenses decreased during the six months ended June 30, 2023 compared to the same period in 2022 primarily due to lower spending on SP-2577 offset by higher spending in SP-3164 in 2023.

We expect total research and development expenses and research and development expense for each of our research and development projects to decrease in the remainder of 2023 as compared to the prior year and into 2024 as compared to 2023 as we evaluate the development strategy for our product candidates, and explore and evaluate strategic alternatives.

		<u>SP-2577</u>					<u>SP-3164</u>		
Research and development costs by candidates				Six months	ende	d June 30,			
and by categories:		2023		2022		2023		2022	
Outsourced research and development costs	\$	1,257,762	\$	2,650,433	\$	2,543,587	\$	459,229	
Employee-related costs		1,055,618		1,137,836		103,066		88,766	
Manufacturing and laboratory costs		105,575		580,294		1,011,832		456,589	
In-process research and development costs				<u> </u>				1,987,900	
Total research and development costs	\$	2,418,955	\$	4,368,563	\$	3,658,485	\$	2,992,484	

#### General and Administrative Expenses

General and administrative expenses were \$3.3 million during the six months ended June 30, 2023, compared to \$3.5 million for the six months ended June 30, 2022, resulting from lower proxy service expense, investor relations services expense and overall compensation and benefit costs in current year, partially offset by higher legal cost and business development cost.

# **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. In August 2023, we commenced a process to explore and evaluate strategic alternatives to enhance shareholder value, which could result in a fundamental transaction as defined by the warrant agreement. The terms of the outstanding warrants require us, upon the consummation of any fundamental transaction to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume our obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of our common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the warrants could also impede our ability to enter into certain transactions or obtain additional financing in the future. In conjunction with our exploration of strategic alternatives, we are exploring opportunities to extend our resources.

As of June 30, 2023, we had \$8.3 million of working capital and our cash and cash equivalents totaled \$11.5 million, which were held in bank deposit accounts and a money market account. Our cash and cash equivalents balance

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decreased during the six months ended June 30, 2023, primarily due to cash used in operating activities, partially offset by the cash received from financing activities. As recently announced, our cost savings plan extends our expected cash runway and enables evaluation and implementation of strategic alternatives. We believe that our \$11.5 million in cash and cash equivalents on hand as of June 30, 2023, is sufficient to fund our current and restructured operations through the fourth quarter of 2023.

To provide the maximum degree of financial flexibility, and subject to our exploration of strategic alternatives, we may consider various potential opportunities to fund future operations and/or modulate liquidity needs, including: (i) seeking various strategic transactions, including a merger, licensing arrangement or sale that provide funding for our programs; (ii) entering into one or more collaborations to offset costs; (iii) reducing our expenditures on all business activities and/or restructuring our operations and reducing staff. If we are unable to execute on these activities, we may be forced to evaluate additional alternatives including a wind down of our operations.

We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize our product candidate. At the same time, subject to our exploration of strategic alternatives, 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 candidate, 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.

To date, we have secured capital from the sale of equity and grant revenue. Until we can generate a sufficient amount of revenue from our products, if ever, 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 acceptable to us. If we are unable to obtain additional financing, we may be required to significantly delay, scale back or discontinue the development or commercialization of our product candidate. Furthermore, we may be unable to complete a collaboration, or if we do, we may be forced to relinquish valuable future product rights.

#### Cash Flows

	Six months ended June 30,		
	2023		2022
Net cash (used in) provided by in:			
Operating activities	\$ (7,585,882)	\$	(7,140,445)
Investing activities	_		(1,500,000)
Financing activities	7,020,890		2,073,070
Net decrease in cash and cash equivalents	\$ (564,992)	\$	(6,567,375)

#### **Operating Activities**

Net cash used in operating activities was \$7.6 million in the current period, an increase of approximately \$0.4 million from the same period a year ago. The increase is primarily due to a decrease in accounts payable balances during the current period.

#### **Investing Activities**

Net cash used in investing activities was \$1.5 million in the prior period, for the cash portion of the purchase price for the acquisition of inprocess research and development technology SP-3164. There was no such transaction during the same period in 2023.

#### Financina Activities

Net cash provided by financing activities for the six months ended June 30, 2023 was \$7.0 million, compared to \$2.1 million for the same period of the year 2022. This results from the Company's sale of 696,271 common shares

under its ATM offering and 330,000 common shares and 3,306,364 Pre-Funded Warrants in a transaction that closed on May 16, 2023. Please refer to NOTE 7 for more detailed information.

## 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 27, 2023.

Readers should refer to our Annual Report on Form10-K filed with SEC on March 27, 2023, 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

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

#### Item 4. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2023. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

During the three months ended June 30, 2023, 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

Investing in our stock involves a high degree of risk. You should carefully consider the following discussion of risk factors in its entirety. In addition to the other information set forth in this report, you should carefully consider the information under "Part I, Item 1A- Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 27, 2023.

Our activities to evaluate and pursue strategic alternatives may not result in any definitive transaction or enhance shareholder value, and may create a distraction for our management and uncertainty that may adversely affect our operating results and business.

We have commenced a process to evaluate strategic alternatives in order to enhance stockholder value, including the possibility of an acquisition, merger, reverse merger, other business combination, sales of assets, licensing, or other strategic transactions involving the Company. We have engaged Canaccord Genuity, LLC as our financial advisor to assist us in this process. In connection with the evaluation of strategic alternatives, we are evaluating opportunities to extend our resources and have reduced our headcount by more than 50% of our positions. We expect to devote significant time and resources to identifying and evaluating strategic transactions and this process may create a distraction, uncertainty or the loss of business opportunities, which may adversely affect our operating results and business. We have incurred, and may in the future incur, significant costs associated with identifying, evaluating and negotiating potential strategic alternatives, such as legal, financial advisor and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed, decreasing cash available for use in our business. There can be no assurance that the process to evaluate strategic alternatives will result in agreements or transactions. The current market price of our common stock may reflect a market assumption that a transaction will occur, and a failure to complete a transaction could result in a negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives. Even if we negotiate a definitive agreement, there can be no certainty that any transaction will be completed, be on attractive terms, enhance stockholder value or deliver the anticipated benefits, and successful integration or execution of the strategic alternatives will be subject to additional risks. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders. If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

If we do not successfully complete a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no guarantee that the process to identify a strategic transaction will result in a successfully completed transaction. If no transaction is completed, our board of directors may decide that it is in the best interest of our stockholders to dissolve our company and liquidate our assets. In that event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations and evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a dissolution, liquidation or winding up of our company.

If we fail to comply with the continued listing standards of the Nasdaq Capital Market, our common stock could be delisted. If it is delisted, our common stock and the liquidity of our common stock would be impacted.

The continued listing of our common stock on Nasdaq is contingent on our continued compliance with a number of listing standards. On August 7, 2023, the closing price of our common stock was \$0.86 per share, which is below

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the minimum trading price required to maintain listing on Nasdaq. There is no assurance that we will remain in compliance with these standards. Delisting from Nasdaq would significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our common stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

Our cost savings plans and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On August 5, 2023, we approved a cost savings plan intended to preserve capital while we assess potential strategic alternatives. As of the filing of this Quarterly Report on Form 10-Q, the Company estimates that it will incur severance and other employee-related costs of approximately \$1.2 million. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our cost savings efforts due to unforeseen difficulties, delays or unexpected costs. For example, we may incur unanticipated charges not currently contemplated as a result of the cost savings plans. If we are unable to realize the expected operational cost savings from the restructuring, our operating results and financial condition would be adversely affected.

#### Item 5.Other Information.

# Item 2.05 Costs Associated with Exit or Disposal Activities

On August 5, 2023, the Company approved a cost savings plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to explore strategic alternatives and limit its clinical development activities. Execution of the workforce reduction plan is expected to be substantially complete by the end of the fourth quarter of 2023.

The Company expects the charges and spending will be incurred primarily in the third and fourth quarters of 2023. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the cost savings plan. If the Company subsequently determines that it will incur additional significant costs and realignment charges, it will file a Current Report on Form 8-K to disclose such information.

# Item 6. Exhibits

Exhibit number	Description of Document
3.1	Amended and Restated Certificate of Incorporation
3.2	Certificate of Amendment to Certificate of Incorporation filed with the Secretary of State of Delaware on July 18, 2019
3.3	Certificate of Amendment to Certificate of Incorporation filed with the Secretary of State of Delaware on October 14, 2022
3.4	Amended and Restated Bylaws, effective July 19, 2019
3.5	Amendment to Amended and Restated Bylaws of the Registrant, effective April 1, 2022
10.1	Form of Securities Purchase Agreement
10.2	Form of Registration Rights Agreement
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, 2023, 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.
104	Cover Page Interactive Data File (embedded within the inline XBRL document and included in Exhibit 101)

<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)

August 10, 2023 Date:

# 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-O 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 10, 2023

# 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 Chief Financial Officer (Principal Financial and Accounting Officer)

August 10, 2023

#### 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, 2023 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

President and Chief Executive Officer (Principal Executive Officer)

/s/ Mark J. Rosenblum

Mark J. Rosenblum

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

August 10, 2023

August 10, 2023