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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2022
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from to

Commission File Number: 001-36812

SALARIUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**46-5087339**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

(832)804-9144
Registrant's telephone number, including area code

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

Securities registered pursuant to Section 12(b) of the Act

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes ☐ No ☒

As of November 7, 2022, there were 2,278,227 shares of common stock outstanding.

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

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:

- the extent to which the COVID-19 pandemic impacts our business, our customers’ businesses, the medical community and the global economy;
- the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;
- the imposition of restrictions imposed by the FDA on the company’s Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas following the SUSAR, including the partial clinical hold on November 1, 2022;
- our ability to resume enrollment in the Phase 1/2 trial of seclidemstat following its review of the available data surrounding the SUSAR;
- the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials and regulatory submissions;
- fluctuations in our operating results;

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

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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

	9/30/2022 (Unaudited)	12/31/2021
Assets		
Current assets:		
Cash and cash equivalents	$ 16,820,220	$ 29,214,380
Prepaid expenses and other current assets	1,145,812	949,215
Total current assets	17,966,032	30,163,595
Grants receivable from CPRIT	1,610,490	1,610,490
Other assets	146,461	193,874
Goodwill	—	8,865,909
Total assets	$ 19,722,983	$ 40,833,868
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,716,580	$ 1,543,096
Accrued expenses and other current liabilities	1,393,867	567,787
Total liabilities	3,110,447	2,110,883
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; 2,249,371 and 1,809,593 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	224	181
Additional paid-in capital	74,046,524	70,919,996
Accumulated deficit	(57,434,212)	(32,197,192)
Total stockholders' equity	16,612,536	38,722,985
Total liabilities and stockholders' equity	$ 19,722,983	$ 40,833,868

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	**2021**	**2022**	**2021**
Revenue:				
Grant revenue	$ —	$ —	$ —	$ 1,840,216
Operating expenses:				
Research and development	3,790,123	2,015,930	11,151,170	5,852,887
General and administrative	1,832,032	1,730,730	5,346,181	4,655,404
Loss on impairment of goodwill	8,865,909	—	8,865,909	—
Total operating expenses	14,488,064	3,746,660	25,363,260	10,508,291
Loss before other income (expense)	(14,488,064)	(3,746,660)	(25,363,260)	(8,668,075)
Change in fair value of warrant liability	335	9,073	12,570	5,205
Interest income (expense), net	78,272	487	113,670	(495)
Loss from continuing operations	**(14,409,457)**	**(3,737,100)**	**(25,237,020)**	**(8,663,365)**
Net loss	**$ (14,409,457)**	**$ (3,737,100)**	**$ (25,237,020)**	**$ (8,663,365)**
Loss per common share — basic and diluted	**$ (6.41)**	**$ (2.09)**	**$ (12.13)**	**$ (5.41)**
Weighted-average number of common shares outstanding — basic and diluted	2,247,753	1,792,190	2,081,023	1,602,565

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30	
	2022	**2021**
Operating activities		
Net loss	$ (25,237,020)	$ (8,663,365)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,008	14,387
Loss on impairment of goodwill	8,865,909	—
Equity-based compensation expense	651,296	413,153
In-process research and development technology	1,987,900	—
Change in fair value of warrant liability	(12,570)	(5,205)
Changes in operating assets and liabilities:		
Grants receivable	—	1,769,839
Prepaid expenses and other current assets	(154,192)	(329,799)
Accounts payable	173,486	(618,830)
Accrued expenses and other current liabilities	838,648	(59,774)
Net cash used in operating activities	(12,881,535)	(7,479,594)
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	1,987,375	27,256,384
Proceeds from warrants exercised for cash	—	1,485,351
Payments on note payable	—	(477,028)
Net cash provided by financing activities	1,987,375	28,264,707
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,394,160)	20,785,113
Cash, cash equivalents and restricted cash at beginning of period	29,214,380	11,118,614
Cash, cash equivalents and restricted cash at end of period	$ 16,820,220	$ 31,903,727
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 1,468
Non-cash investing and financing activities:		
Common stock issued for in-process research and development technology	$ 487,900	$ —
Accrued issuance costs for public offering	$ —	$ —

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2020	**952,341**	**$ 95**	**$ 41,588,047**	**$ (19,428,954)**	**$ 22,159,188**
Issuance of equity securities, net	785,088	79	26,849,942	—	26,850,021
Warrants exercised for cash	51,942	5	1,485,346	—	1,485,351
Equity-based compensation expense	—	—	135,379	—	135,379
Net loss	—	—	—	(1,851,896)	(1,851,896)
Balance at March 31, 2021	**1,789,371**	**$ 179**	**$ 70,058,714**	**$ (21,280,850)**	**$ 48,778,043**
Equity-based compensation expense	1,531	—	147,456	—	147,456
Issuance of equity securities for services	247	—	—	—	—
Net loss	—	—		(3,074,369)	(3,074,369)
Balance at June 30, 2021	**1,791,149**	**$ 179**	**$ 70,206,170**	**$ (24,355,219)**	**$ 45,851,130**
Equity-based compensation expense	—	—	130,322	—	130,322
Issuance of equity securities, net	15,749	2	406,361	—	406,363
Net loss	—	—	—	(3,737,100)	(3,737,100)
Balance at September 30, 2021	**1,806,898**	**181**	**70,742,853**	**(28,092,319)**	**42,650,715**
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	—	—	—	(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**
Equity-based compensation expense	—	—	134,316	—	134,316
Issuance of equity securities for services	4,802	—	3,548	—	3,548
Net loss	—	—	—	(14,409,457)	(14,409,457)

Balance at September 30, 2022	**2,249,371**	**224**	**74,046,524**	**(57,434,212)**	**16,612,536**

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 Company is developing two classes of drugs that address gene dysregulation: epigenetic 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) seclidemstat (SP-2577), a targeted protein inhibitor and 2) SP-3164, a targeted protein degrader. 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 oncology drug. 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 intends to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans. The Company believes that its $16.8 million in cash and cash equivalents on hand as of September 30, 2022, is sufficient to fund its anticipated operations into the second half of 2023.

Recent Developments

Reverse Stock Split

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 as of October 14, 2022. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

Partial Clinical Hold

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

Company with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

Acquisition and Strategic Collaboration Agreement

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

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying 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, 2021 included elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2022. In the opinion of management, the unaudited interim financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company’s financial position as of September 30, 2022 and the results of operations for the three and nine months ended September 30, 2022 and 2021. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2021 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 nine months ended September 30, 2022 and 2021.

Goodwill

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

Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The Company utilizes the option to perform a qualitative assessment for its reporting unit and if the Company concludes it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company utilizes the two-step quantitative assessment. The Company's qualitative assessment is sensitive to assumptions related to potential adverse events and circumstances, including current market trends in control premiums and involves judgement in determining comparable peer companies to include in the control premium evaluation. The Company recorded goodwill impairment loss of $8.9 million during the three and nine month ended September 30, 2022. Please refer to NOTE 9 for further discussion.

Financial Instruments and Credit Risks

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

Warrants

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

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

Equity-Based Compensation

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

The Company uses the Black-Scholes option valuation model to estimate the fair value of the stock-based compensation and incentive units. Assumptions utilized in these models 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, and (iii) 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 approximately 706,400 and 381,248 shares as of September 30, 2022 and 2021, respectively.

Income Taxes

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

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and

circumstances. As of September 30, 2022 and December 31, 2021, the Company did not have any significant uncertain tax positions and no interest or penalties have been charged. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company is subject to routine audits by taxing jurisdictions.

Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement of all expected credit losses for financial assets including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments - Credit Losses. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 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 will be effective for the Company during the first quarter of 2023. The Company is in the process of assessing the impact adoption will have on its consolidated financial statements.

NOTE 3. 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 $1.6 million at both September 30, 2022 and December 31, 2021.

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid clinical trial expenses	$ 11,185	$ 97,557
Prepaid insurance	885,974	678,672
Other prepaid and current assets	248,653	172,986
Total prepaid expenses and other current assets	$ 1,145,812	$ 949,215

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

NOTE 5. COMMITMENTS AND CONTINGENCIES

License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which, the Company acquired 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.

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

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

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 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 ("Flex Warrants"), which are measured at fair value on a recurring basis for the nine months ended September 30, 2022:

Description	Balance at December 31, 2021	Change in Fair Value	Balance at September 30, 2022
Warrant liability	$ 14,518	$ 12,570	$ 1,948

NOTE 7. STOCKHOLDERS' EQUITY

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

Common Stock Issuances

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

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

On February 5, 2021, the Company entered into an At the Market Offering Agreement (the "Sales Agreement") with Ladenburg Thalmann & Co. Inc. ("Ladenburg"). Under the Sales Agreement the Company was able to issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to $6.3 million (the "ATM Shares") with Ladenburg acting as an agent for 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. No shares were issued under the Sales Agreement during the nine months ended September 30, 2022. During the nine months ended September 30, 2021, the Company issued approximately 128,569 shares under the Sales Agreement for gross proceeds of $6.7 million.

On March 8, 2021, the Company completed a public offering of approximately 672,269 shares of its common stock at a price to the public of $34.2125 per share. Total gross proceeds from the offering were approximately $23.0 million prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

Warrants Exercised for Cash

The Company has five-year warrants outstanding that were issued in February 2020 and subsequently modified in December 2020 in connection with the issuance of additional inducement warrants. The warrants are exercisable at a price per share of $28.75. The inducement warrants expire on June 11, 2026 and are exercisable at a price per share of $29.55. The Company has 5.5 year warrants 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.

During the nine months ended September 30, 2022, no warrants were exercised. During the nine months ended September 30, 2021, the Company issued approximately 51,942 common shares as a result of warrant exercises, and received cash proceeds of approximately $1.5 million. As of September 30, 2022, approximately 590,087 warrants remain outstanding, excluding Flex Warrants and Wedbush Warrants.

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 September 30,

2022, there were approximately 45,468 shares remaining available for the grant of option awards under the 2015 Plan.

During the nine-month periods ended September 30, 2022 and 2021, the Company awarded 51,360 and 3,160 stock options, respectively, 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 nine-months periods ended September 30, 2022 and 2021 was $0.5 million and $0.1 million, respectively, which has been estimated with the following assumptions on the grant date.

	Nine Months Ended September 30	
	2022	2021
Risk-free interest rate	1.62%-1.70%	0.93% - 1%
Volatility	125.19% 126.42%	130.44% 133.35%
Expected life (years)	5.00-6.00	6.00
Expected dividend yield	0%	0%

The following table summarizes stock option activity for employees and non-employees for the nine months ended September 30, 2022 and 2021:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	62,559	$69.50	9.47	$175,770
Granted	3,160	$32.50		
Exercised	—			
Forfeited	(1,800)	—		
Expired	—			
Outstanding at September 30, 2021	63,919	$68.75	8.75	$271,540
Exercisable at September 30, 2021	6,261	$231.75	7.74	$34,440
Outstanding at December 31, 2021	63,919	$68.75	8.50	$—
Granted	51,360	$11.75		
Exercised	—			
Forfeited	(5,015)			
Expired	(1,375)			
Outstanding at September 30, 2022	108,889	$23.75	8.53	$—
Exercisable at September 30, 2022	36,301	$35.50	7.88	$—

As of both September 30, 2022 and 2021, there was approximately $1.0 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 2.4 years.

NOTE 9 GOODWILL

The recent decline in the Company's market capitalization, along with other qualitative considerations was determined to be a triggering event for potential goodwill impairment and accordingly, the Company performed the goodwill impairment analysis for the third quarter ended September 30, 2022. In determining the fair value utilized in the goodwill impairment assessment, the Company considers qualitative factors such as changes in strategy, cash flows, the regulatory environment, overall market conditions, as well as the market capitalization of the Company's publicly traded common stock. The Company operates as a single reporting unit and estimates the fair value of its single reporting unit using the Company's market capitalization plus an estimated control premium. Market capitalization is determined by multiplying the shares outstanding on the assessment date by the market price of the Company's common stock. As a result of the impairment assessment during the three months ended September 30, 2022, the Company recorded an impairment charge to write off the entire balance of the goodwill of $8.9 million. The impairment charge was recorded in the consolidated statement of operations and comprehensive loss.

NOTE 10 SUBSEQUENT EVENTS

The Company's management reviewed all material events through the date that the financial statements were issued for subsequent event disclosure consideration. Please refer to Recent Developments in NOTE 1.

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, 2021, filed with the SEC on March 25, 2022. 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, 2021, 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 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: epigenetic inhibitors and targeted protein degraders. Our technologies have the potential to work in both liquid and solid tumors. Our current pipeline consists of: 1) seclidemstat (SP-2577), a targeted LSD1 protein inhibitor, 2) SP-3164, a targeted protein degrader, and 3) a second generation LSD1 inhibitor program in drug discovery.

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 $57.4 million as of September 30, 2022. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. As of September 30, 2022, we had cash and cash equivalents of $16.8 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 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, 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.

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

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

Recent Developments

On October 14, 2022, we filed a Certificate of Amendment to our restated certificate of incorporation (as amended, the "Certificate of Amendment"), with the Secretary of State of Delaware, to effect a one-for-25 reverse stock split of our issued and outstanding shares of common stock at 5:00 p.m. Eastern Time on that date. Beginning with the opening of trading on October 17. 2022, our common stock was traded on Nasdaq Capital Market on a split-adjustment basis under a new CUSIP number 79400X305.

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

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. Based on SP-2577's proposed mechanism of action, preclinical data, and clinical data from our earlier Advanced Solid Tumor trial, we expanded the Ewing sarcoma dose expansion trial to include a cohort of Ewing-related sarcomas (also referred to as FET-translocated sarcomas). Ewing sarcoma and FET-translocated sarcomas are rare cancers that may provide a speed-to-market development approach. In addition, as part of our market expansion strategy, in 2021 we initiated an Investigator Initiated Trial with the MD Anderson Cancer Center that is 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 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.

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 IKZF1 and IKZF3, along with other proteins, resulting in both direct anti-cancer activity and immune-modulating properties. SP-3164 has potential to treat both hematologic and solid tumors and is currently in IND-enabling studies. We have completed the pre-IND meeting process and plan to submit an IND application to the FDA in the first half of 2023

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

Special Note About Coronavirus (COVID-19)

The ongoing COVID-19 coronavirus pandemic (the "Pandemic") has had a significant effect on the United States, global economies, and business worldwide. While we have thus far experienced minimal disruptions from the Pandemic, the duration and full extent to which the Pandemic impacts our business and financial condition depends on future developments that are highly uncertain, subject to change and are difficult to predict, including new information that may emerge concerning the Pandemic, and may cause intermittent or prolonged periods of interruptions to our clinical operations. We are continuously monitoring the Pandemic and its potential effect on our financial position, results of operations and cash flows. This uncertainty could have an impact in future periods on certain estimates used in the preparation of our periodic financial results. Uncertainty around the extent and length of time of the Pandemic, and any future related financial impact cannot be reasonably estimated at this time.

Results of Operations

Three months ended September 30, 2022 Compared to the Three months ended September 30, 2021

The following table sets forth the condensed consolidated results of our operations for the three months ended September 30, 2022 compared to September 30, 2021.

	Three months ended September 30,		$ Change
	2022	2021	
Grant revenue	$ —	$ —	$ —
Research and development expenses	3,790,123	2,015,930	1,774,193
General and administrative expenses	1,832,032	1,730,730	101,302
Loss on Impairment of Goodwill	8,865,909	—	8,865,909
Change in fair value of warrant liability	335	9,073	(8,738)
Interest income(expense), net	78,272	487	77,785
Net loss	$ (14,409,457)	$ (3,737,100)	**$ (10,672,357)**

Grant Revenue

Grant revenue, which was derived solely from the CPRIT grant, was $0 for the three months ended September 30, 2022 resulting from the completion of CPRIT available funding under the grant during the second quarter of 2021. We have reached the maximum amount of the eligible spending that can be reimbursed from CPRIT.

As of September 30, 2022, we continue to expect to receive $1.6 million from the grant.

Research and Development Expenses

Research and development expenses increased during the three months ended September 30, 2022 compared to the same periods in 2021 primarily due to spending on SP-3164, which was acquired in January 2022. Overall costs associated with SP-2577 decreased by approximately $0.3 million compared to the same period in the prior year mainly driven by lower manufacturing cost.

Research and development costs by candidates and by categories:	SP-2577		SP-3164	
	Three months ended September 30,			
	2022	2021	2022	2021
Outsourced research and development costs	$ 1,047,906	$ 1,128,499	982,646	$ —
Employee-related costs	510,877	420,195	48,049	—
Manufacturing and laboratory costs	136,751	467,236	1,063,894	—
Total research and development costs	**$ 1,695,534**	**$ 2,015,930**	**$ 2,094,589**	**$ —**

General and Administrative Expenses

General and administrative expenses increased slightly to $1.8 million during the three months ended September 30, 2022 from $1.7 million for the three months ended September 30, 2021.

Loss on Impairment of Goodwill

During the current quarter, we recorded a non cash impairment charge of $8.9 million. There was no impairment charge during the three months ended September 30, 2021.

Nine Months Ended September 30, 2022 Compared to the Nine Months Ended September 30, 2021

The following table sets forth the condensed consolidated results of our operations for the nine months ended September 30, 2022 compared to September 30, 2021.

	Nine months ended September 30,		$ Change
	2022	2021	
Grant revenue	$ —	$ 1,840,216	$ (1,840,216)
Research and development expenses	11,151,170	5,852,887	5,298,283
General and administrative expenses	5,346,181	4,655,404	690,777
Loss on Impairment of Goodwill	8,865,909	—	8,865,909
Change in fair value of warrant liability	12,570	5,205	7,365
Interest income(expense), net	113,670	(495)	114,165
Net loss	$ (25,237,020)	$ (8,663,365)	$ (16,573,655)

Grant Revenue

Grant revenue, which was derived solely from the CPRIT grant, was $0 for nine months ended September 30, 2022 resulting from the completion of CPRIT available funding under the grant during the second quarter of 2021. We have 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 nine months ended September 30, 2022 compared to the same periods in 2021 resulting primarily from the purchase of SP-3164 as an in-process research and development technology and continued spending on SP-3164 drug development. Cost associated with SP-2577 is slightly higher compared to the prior year, mainly driven by higher outsourced research and development costs, personnel costs and clinical trial costs, offset by lower manufacturing cost.

Research and development costs by candidates and by categories:	SP-2577		SP-3164	
	Nine months ended September 30,			
	2022	2021	2022	2021
Outsourced research and development costs	$ 3,698,339	$ 3,225,900	$ 1,441,875	$ —
Employee-related costs	1,648,713	1,138,833	136,815	—
Manufacturing and laboratory costs	717,045	1,488,154	1,520,483	—
In process research and development costs	—	—	1,987,900	—
Total research and development costs	**$ 6,064,097**	**$ 5,852,887**	**$ 5,087,073**	**$ —**

General and Administrative Expenses

General and administrative expenses increased to $5.3 million during the nine months ended September 30, 2022 from $4.7 million for the nine months ended September 30, 2021 due to higher personnel costs, legal cost and public company cost offset by lower professional services related 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.

As of September 30, 2022, we had $14.9 million of working capital and our cash and cash equivalents totaled $16.8 million, which were held in bank deposit accounts and a money market account. Our cash and cash equivalents balance decreased during the nine months ended September 30, 2022, primarily due to cash used in operating and investing activities, offsetting by the cash received from financing activities. We believe that our $16.8 million in cash and cash equivalents on hand as of September 30, 2022, is sufficient to fund our anticipated operations into the second half of 2023.

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, 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, 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.

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

	Nine months ended September 30,	
	2022	**2021**
Net cash (used in) provided by in:		
Operating activities	$ (12,881,535)	$ (7,479,594)
Investing activities	(1,500,000)	—
Financing activities	1,987,375	28,264,707
Net (decrease) increase in cash and cash equivalents	$ (12,394,160)	$ 20,785,113

Operating Activities

Net cash used in operating activities was $12.9 million in the current period, an increase of approximately $5.4 million from the same period a year ago. The increase is primarily due to higher research and development cost incurred in current year.

Investing Activities

Net cash used in investing activities was $1.5 million in the current period for the cash portion of the purchase price for the acquisition of in-process research and development technology SP-3164. There was no such transaction during the same period in 2021.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was $2.0 million, compared to $28.3 million for the same period of the year 2021. This is due to the Company's completion of common stock sales during the nine months ended September 30, 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 nine months ended 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 25, 2022.

Readers should refer to our Annual Report on Form10-K filed with SEC on March 25, 2022, 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 September 30, 2022. 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 September 30, 2022, 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 September 30, 2022, 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, 2021, filed with the SEC on March 25, 2022, 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. 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 25, 2022.

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

On October 18, 2022, we announced that per protocol design, we voluntarily paused new patient enrollment in our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas. The pause in new patient enrollment was due to a metastatic FET-rearranged sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). At the time, we also announced that our independent Safety Review Committee for the clinical trial determined that patients currently receiving seclidemstat treatment could continue treatment after consulting with their physician.

During a conference call with the US Food and Drug Administration (FDA) on Tuesday, November 1, 2022, the FDA informed us that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET-rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, FDA informed us that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA’s clinical hold procedures provide us with an administrative process to work with the FDA to analyze the available data, adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment.

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

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

We will continue to require substantial additional capital to fund our clinical activities and operations and the impact of the COVID-19 coronavirus 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 $12.8 million for the year ended December 31, 2021, and we have incurred a net loss of $14.4 million and $25.2 million for the three months ended September 30, 2022 and nine months ended September 30, 2022, 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 candidate.

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 candidate, 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 $14.5 million since inception of the grant. The term of the CPRIT agreement was extended through November 30, 2022. We currently have a $1.6 million receivable due from CPRIT on our September 30, 2022 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.

Item 6. Exhibits

Exhibit number	Description of Document
3.1	Amended and Restated Certificate 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
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 September 30, 2022, 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.

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

SIGNATURES

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

SALARIUS PHARMACEUTICALS, INC.

By: /s/ David J. Arthur

David J. Arthur
President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Mark J. Rosenblum

Mark J. Rosenblum
Chief Financial Officer and Executive Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)

Date: November 10, 2022

Exhibit 31.1

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)

November 10, 2022

Exhibit 31.2

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)

November 10, 2022

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Salarius Pharmaceuticals, Inc. (the "Company") for the fiscal period ended September 30, 2022 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
November 10, 2022 President and Chief Executive Officer (Principal Executive Officer)

/s/ Mark J. Rosenblum
Mark J. Rosenblum
Executive Vice President and Interim Chief Financial Officer
November 10, 2022 (Principal Financial Officer and Principal Accounting Officer)