UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 29, 2020

SALARIUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36812 (Commission File Number)

46-5087339 (I.R.S. Employer Identification No.)

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

77021 (Zip Code)

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

(Former	N/A name or former address, if changed since last report.)			
ck the appropriate box below if the Form 8-K filing is owing provisions (<u>see</u> General Instruction A.2. below)	, ,	bligations of the registrant under any of the		
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)				
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)				
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))				
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))				
Securities	registered pursuant to Section 12(b) of the Act	:		
Title of each class	Trading symbol(s)	Name of each exchange on which registered		

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ⊠

Item 2.02 Results of Operations and Financial Condition.

Salarius Pharmaceuticals, Inc. (the "Company") has provided preliminary financial results for the quarter ended June 30, 2020, included in Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

The information in Item 2.02 of this Current Report on Form 8-K, including the preliminary financial results for the quarter ended June 30, 2020 contained in Exhibit 99.2, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 (the "Securities Act"), except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On July 29, 2020, the Company has made available on its website (www.salariuspharma.com) an investor presentation, which provided information to investors about the Company, a copy of which is furnished herewith as Exhibit 99.3. The information contained in the investor presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. All information in Exhibit 99.3 is presented as of the particular date or dates referenced therein, and the Company does not undertake any obligation to, and disclaims any duty to, update any of the information provided therein.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.3, shall not be deemed to be filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On July 29, 2020, the Company announced that it has commenced an underwritten public offering of its common stock. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company has updated its disclosures. The disclosures are filed herewith as Exhibit 99.2 and are incorporated by reference herein, except for the preliminary financial results for the quarter ended June 30, 2020, which are furnished, and shall not be deemed filed, pursuant to Item 2.02 of this Current Report on Form 8-K.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding: the Company's preliminary estimated financial results; the impact of the COVID-19 pandemic on the Company's business and the actions it may take in response thereto; the impact of the COVID-19 pandemic on third parties with which the Company works; the Company's anticipated use of proceeds; the Company's need for additional financing and expectations as to ability to obtain such financing and the potential impact of any future financing; the Company's expectations as to funds available under the CPRIT grant; expectations as to the Company's clinical trials, future operations, and future operating results and expense levels; and the Company's prospects, plans, and objectives. The Company has based these forward-looking statements on its current expectations and projections about future events and trends that the Company believes may affect its financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial requirements. In addition, reported results, including preliminary estimated results, should not be considered as an indication of future performance. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those reflected or otherwise implied in such forward-looking statements. These risks and uncertainties include, but are not limited to: the effect of the COVID-19 pandemic on the Company's business and the success of any measures the Company has taken or may take in the future in response thereto; its ability to manage its business plans, strategies, and outlooks and any business-related forecasts or projections; the availability of sufficient resources to meet its business objectives and operational requirements;

the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; the risk that it may not obtain or maintain sufficient levels of reimbursement for its clinical trials and product development, including from CPRIT; the Company's history of losses; the fact that the results of earlier studies and trials may not be predictive of future clinical trial results; the Company's quarter-end closing procedures and finalization of its quarterly financial results; the ability to protect its intellectual property rights; risks related to the drug development and the regulatory approval process; the impact of competitive products and technological changes; the impact of new legislation, regulations, or judicial decisions on the Company's business; other legal and regulatory uncertainties; its ability to compete against third parties; its ability to manage future growth; the market price of the Company's common stock and the Company's ability to maintain the listing of its common stock on Nasdaq; foreign currency exchange rate fluctuations; the impact of economic conditions, unemployment levels, and loss of health insurance benefits on the Company's business; its ability to compete; and other risks set forth in the Company's filings with the Securities and Exchange Commission, including the risks set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. These forward-looking statements speak only as of the date hereof, and the Company disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits. (d) Exhibits

Exhibit No. Description 99.1 Press Release dated July 29, 2020. 99.2 Disclosures. Investor Presentation. 99.3

SIGNATURE

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

SALARIUS PHARMACEUTICALS, INC.

Date: July 29, 2020 By: /s/ David J. Arthur

Name: David J. Arthur

Title: President and Chief Executive Officer

Salarius Announces Proposed Public Offering of Common Stock

Houston, Texas, July 29, 2020 (GLOBE NEWSWIRE) – Salarius Pharmaceuticals, Inc. (Nasdaq: SLRX), a clinical-stage oncology company targeting cancers caused by dysregulated gene expression, today announced that it has commenced an underwritten public offering of shares of its common stock. All of the shares are being offered by Salarius. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Ladenburg Thalmann & Co. Inc. is acting as sole book-running manager in connection with the public offering.

A shelf registration statement on Form S-3 (File No. 333-231010) relating to the shares was filed with the Securities and Exchange Commission (the "SEC") and was declared effective by the SEC on May 17, 2019. A copy of the preliminary prospectus supplement and accompanying prospectus relating to the offering, when available, may be obtained be obtained at the SEC's website at www.sec.gov or from Ladenburg Thalmann & Co. Inc., Attn: Prospectus Department, 277 Park Avenue, 26th Floor, New York, New York 10172, by calling (212) 409-2000.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Salarius Pharmaceuticals, Inc.

Salarius Pharmaceuticals, Inc. is a clinical-stage oncology company targeting cancers caused by dysregulated gene expression, or epigenetic causes of cancers and is developing treatments for patients that need them the most. Epigenetics refers to the regulatory system that affects gene expression. Salarius' lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Fast Track Designation Orphan Drug Designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. Salarius is also developing Seclidemstat for a number of cancers, with a second Phase 1/2 clinical study in advanced solid tumors, including prostate, breast, and ovarian cancers.

Forward-Looking Statements

This press release contains forward-looking statements within the Private Securities Litigation Reform Act of 1995, including statements that relate to the offering, the expected completion of the offering, and other information that is not historical information. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks and uncertainties related to completion of the public offering on the anticipated terms or at all, market conditions, the impact of the COVID-19 pandemic, and the satisfaction of customary closing conditions related to the public offering. More information about the risks and uncertainties faced by Salarius is contained in the sections captioned "Risk Factors" in the preliminary prospectus supplement and the accompanying prospectus related to the public offering filed with the SEC, including the documents incorporated by reference therein. Salarius disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Investor Relations

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Recent Developments

Phase 1/2 Clinical Trial

We recently announced the expansion of our ongoing clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma to include additional select sarcomas. The current Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma is an open-label dose-finding trial intended to characterize the pharmacokinetics ("PK") and initial safety profile of seclidemstat, and also determine the maximum tolerated dose ("MTD"). Once MTD is established, the trial is expected to enter a dose expansion phase that will enroll up to 20 Ewing sarcoma patients to expand the safety and PK profile of seclidemstat and assess preliminary efficacy data. Under the planned amendment to the trial protocol, a second cohort of the expansion phase will enroll up to 30 additional patients with either myxoid liposarcoma, desmoplastic small round cell tumors or other Ewing-related sarcomas.

Seclidemstat's potential as a treatment for Ewing-related sarcomas is supported by pre-clinical data and early clinical data observations from the ongoing Phase 1/2 clinical trial of seclidemstat in patients with relapsed or refractory Ewing sarcoma. A refractory Ewing sarcoma patient treated with seclidemstat for six months demonstrated a reduction of over 80% in prospectively defined target lesions. Target lesions generally represent a patient's largest measurable tumors. However, at eight weeks, an increase in non-target lesions resulted in an overall patient classification of progressive disease as defined by Responsive Evaluation Criteria in Solid Tumors (RECIST).

COVID-19 Impact

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

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

On April 13, 2020, we were granted a loan of approximately \$180,000 from Paycheck Protection Program established under the CARES Act. The loan matures on April 13, 2022 and bears interest at a rate of 0.5% per annum. The loan will be forgiven if we use it to pay payroll costs including benefit, mortgage interest, rent, and utilities payment over the eight weeks after obtaining the loan, by submitting a request to the lender that is servicing the loan

Preliminary Results

Our estimated unaudited financial results as of and for the three and six months ended June 30, 2020 presented below are preliminary, estimated, and unaudited, and are subject to completion by management of our financial statements as of and for the quarter ended June 30, 2020, including the completion of our quarter-end closing procedures and further financial review. We have provided ranges for the estimated preliminary financial results described below primarily because the financial closing procedures for the quarter ended June 30, 2020 are not yet complete as of the date of this prospectus supplement. The preliminary financial and business information presented below has been prepared by and is the responsibility of our management and is based upon information available to us as of the date hereof. Our independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial information. Accordingly, our independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto. These preliminary estimates are not a comprehensive statement of our financial results for this period and should not be viewed as a substitute for interim financial statements prepared in accordance with generally accepted accounting principles.

Our actual results may vary materially from these preliminary estimates due to, among other factors, the completion of our quarter-end closing procedures, review adjustments, and other developments that may arise between now and the time our financial results for the period are finalized. Factors that could cause actual results to differ from those described below are set forth herein and under "Risk Factors" in this prospectus supplement and the accompanying prospectus, and in the documents incorporated herein and therein by reference. Accordingly, you should not place undue reliance upon these preliminary estimates. Furthermore, the preliminary estimates should not be viewed as a substitute for quarterly financial statements prepared in accordance with GAAP. In addition, these preliminary results for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be achieved for the remainder of the fiscal year ending December 31, 2020 or in any future period, due to various factors, including the impact of the ongoing COVID-19 pandemic. There can be no assurance that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within our control. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019. Complete quarterly results will be included in our Quarterly Report on Form 10-Q for the six months ended June 30, 2020.

Preliminary estimated second quarter 2020 results are summarized below:

- Revenue of approximately \$1.1 million to \$1.3 million and approximately \$2.3 million to \$2.5 million for the three and six months ended June 30, 2020, respectively;
- Total operating expenses of approximately \$3.0 million to \$3.2 million and approximately \$6.5 million to \$6.7 million for the three and six months ended June 30, 2020, respectively;
- Net loss of approximately \$1.7 million to \$1.9 million and approximately \$3.7 million to \$3.9 million for the three and six months ended June 30, 2020, respectively;
- · Cash, cash equivalents and restricted cash of approximately \$7.1 million to \$7.3 million as of June 30, 2020; and
- Cash used in operating activities of approximately \$6.1 million to \$6.3 million for the six months ended June 30, 2020, primarily related to general and administrative and research and development costs.

RISK FACTORS

The risks described below, as well as those described in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, as well as any amendments thereto reflected in subsequent filings, may materially and adversely impact our business, financial condition, results of operations and prospects and cause the trading price of our common stock to decline. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results, and financial condition.

Risks Related to Our Securities and our Preliminary Estimated Financial Results

Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of our common stock or cause our stock price to decline.

Sales of a substantial number of our shares of common stock in the public markets (including sales of common stock issuable pursuant to the exercise of warrants or stock options or the conversion of our Series A convertible preferred stock), or the perception that such sales could occur, could cause the market price of our shares of common stock to decline and impair our ability to raise capital through the sale of additional equity securities.

As of March 31, 2020, we had outstanding: (a) 13,645,677 shares of common stock; (b) 338,233 shares of common stock issuable upon the exercise of outstanding stock options; (c) 33,592 shares of common stock reserved for future issuance under the 2015 Plan; (d) 81,022 shares of common stock reserved for future issuance under the ESPP; (e) 42,928 shares of common stock issuable upon exercise of a warrant issued to Wedbush; (f) 12,376 shares of common stock issuable pursuant to a professional relations and consulting agreement; (g) 468,694 shares of Series A convertible preferred stock; (h) 9,599,999 shares of common stock issuable upon the exercise of warrants issued in connection with our offering in February 2020; (i) up to \$8.2 million of shares of our common stock available for sale pursuant to the ATM Agreement (subject to limitations under applicable SEC and Nasdaq rules); and (j) 5,164 shares of unvested restricted common stock subject to repurchase by us. In addition, as of January 20, 2020, holders of record of Flex Pharma's common stock as of the close of business on July 18, 2019 had rights to receive warrants exercisable for an aggregate of 142,711 shares of our common stock at an exercise price of \$15.17 per share, which warrants expire on January 20, 2025 (the "Flex Warrants"). We may register the warrants and the underlying shares under the Securities Act of 1933 (the "Securities Act"). In addition, we may, in our sole discretion, elect to deem such warrants exercised on a cashless basis at the closing of an issuance and sale of our common stock in an equity financing with gross proceeds of at least \$10.0 million. If we were to deem such warrants exercised on a cashless basis, the number of common stock to be issued in connection with such deemed cashless exercise will depend on the volume weighted average price of our common stock at the time of closing, and is approximately 1,127,008 shares based on an assumed closing date of July 22, 2020.

Further, at our 2020 annual meeting of stockholders, our stockholders approved an increase of 1,300,000 shares of common stock reserved for future issuance under our 2015 Plan and an increase in the evergreen provision under our ESPP. The evergreen provision provides for an annual increase in the number of shares authorized for issuance under the ESPP on January 1 of each year in an amount equal to the lesser of (i) 1% of the outstanding shares on December 31st of the preceding calendar year, (ii) 40,000, or (iii) any lesser number approved by our Board of Directors. The fixed number of shares in item (ii) of the evergreen provision was increased from 40,000 shares to 100,000 shares for each annual increase occurring after the date of the stockholder approval. Shares issuable under our 2015 Plan and the ESPP will be registered on a Form S-8 registration statement and will therefore be eligible for sale in the public markets by non-affiliates, as well as by affiliates pursuant to Rule 144 of the Securities Act. Sales of stock by any of our directors and executive officers, or the perception such sales may occur, could also have a material adverse effect on the trading price of our common stock

The terms of the Series A convertible preferred stock and the warrants issued in our offering in February 2020 could impede our ability to enter into certain transactions or obtain additional financing.

The terms of the Series A convertible preferred stock and the warrants issued in our offering in February 2020 require us, upon the consummation of any "fundamental transaction" (as defined in the securities), to, among other

obligations, cause any successor entity resulting from the fundamental transaction to assume all of our obligations under the Series A convertible preferred stock and such warrants and the associated transaction documents. In addition, holders of Series A convertible preferred stock and such warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of our common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the Series A convertible preferred stock and such warrants could also impede our ability to enter into certain transactions or obtain additional financing in the future.

Terms of subsequent financings may adversely impact our stockholders.

To finance our future business plans and working capital needs, we will need to raise funds through the issuance of equity or debt securities. Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock and warrants could be reduced. A financing could involve one or more types of securities including common stock, convertible debt, or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be senior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock and the value of any outstanding warrants could be negatively impacted.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, we have no intention of paying any such dividends in the foreseeable future.

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

On April 9, 2020, we were notified (the "Notice") by Nasdaq Stock Market, LLC ("Nasdaq") that on April 8, 2020 the average closing price of our common stock over the prior 30 consecutive trading days had fallen below \$1.00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). We were subsequently notified by Nasdaq on June 15, 2020 that we have regained compliance with the Minimum Bid Requirement. However, we cannot assure you that we will continue to comply with the continued listing standards of Nasdaq. To the extent that we are unable to maintain listing compliance or are unable to resolve any listing deficiency in the future, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock. If for any reasons, Nasdaq should delist our common stock, and if our common stock is not then eligible for quotation on another market or exchange, trading of shares of our common stock could be conducted in the over-the-counter markets. In such event, a reduction in some or all of the following may occur, each of which could materially and adversely affect our stockholders:

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

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

Our actual results for the second quarter of 2020 may be different than the preliminary estimated results included elsewhere herein.

Our preliminary estimated results for the second quarter of 2020 are unaudited and subject to change as we close our books and complete the quarter end closing process, and prepare financial statements for the quarter. Preliminary estimated financial results are inherently subject to business, economic, regulatory, market, financial and competitive uncertainties and contingencies and other future events, as well as matters specific to our business, all of which are difficult to predict and many of which are beyond our control. The inclusion of preliminary estimated financial information herein should not be regarded as an indication that we consider such preliminary estimated financial information to be predictive of actual or future results, in particular in light of the COVID-19 pandemic. Actual results for the quarter may be materially different than the preliminary estimated results presented and our estimated preliminary results should not be relied upon as being necessarily indicative of actual results, and you are cautioned not to place undue reliance on this preliminary financial information. Furthermore, the preliminary financial results do not take into account any circumstances or events occurring after the date they were prepared.

Risks Related to the Impact of the COVID-19 Pandemic on our Company

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

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

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

a global economic recession or depression that could significantly and negatively impact our business or those of third parties upon which we rely for services and supplies;

constraints on our ability to conduct our operations and our preclinical studies and clinical trials;

- delays in our ability to extend the term of the CPRIT grant;
 reduced productivity in our business operations, research and development, marketing, and other activities;
 disruptions to our third-party manufacturers and suppliers;
- increased costs resulting from WFH or from our efforts to mitigate the impact of COVID-19; and
- reduced access to financing to fund our operations due to a deterioration of credit and financial markets.

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

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

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception. Our net losses were \$6.9 million and \$2.1 million for the year ended December 31, 2019 and the three months ended March 31, 2020, respectively. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The development of our product candidates have been funded in part through federal and state grants, including, but not limited to, the funding received from CPRIT. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to, the pace and results of our clinical development efforts, as well as our ability to access the funding remaining available under the CPRIT grant. To date, we have also financed our operations through the sale of equity securities. Our stock price has been negatively impacted in part by the downturn in the financial markets due to the COVID-19 pandemic. This in turn will likely negatively impact our ability to raise funds through equity-related financings. Further, the global economic downturn may impair our ability to obtain additional financing through other means, such as debt financing. There can be no assurance we will be able to secure additional financing on favorable terms to us, or at all. Further any debt financing may contain restrictive covenants which limit our operating flexibility and any equity financing will likely result in additional and possibly significant dilution to existing stockholders. Failure to raise sufficient capital, as and when needed or on commercially reasonable terms, would have a significant and negative impact on our financial condition and our ability to develop our product candidates.

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

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

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

During the course of the development of our product candidates, we have been funded in part through federal and state grants, including but not limited to the funding we received from CPRIT. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, including under the risk factor entitled "Reliance on government funding for our programs may add uncertainty to its research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit its ability to take specified actions, increase the costs of commercialization and production of product candidates developed under those programs and subject it to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations." The CPRIT agreement was awarded in June 2016 and originally provided for a three-year grant award of up to \$18.7 million to fund the development of the LSD-1 inhibitor. As of March 31, 2020, we had received an aggregate of \$9.6 million from the CPRIT grant. A portion of the remaining \$9.1 million CPRIT grant was for a castration-resistant prostate study (approximately \$2.6 million). As we have elected not to pursue this study, we will be requesting from CPRIT approval to redeploy the allocated prostate study funds to our expanded Ewing sarcoma trial. If CPRIT terminates our agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us to repay some or all of the disbursed grant. The term of the CPRIT agreement was extended through May 2020 and we have applied for an extension with a proposed contract end date of November 30, 2020. Although we may apply for government contracts and grants in the future, we may not be successful in obtaining additional grants for any product candidates or programs. Failure to receive

We rely on third parties to conduct our clinical trials, manufacture our product candidates, and perform other services. If these parties are not able to successfully perform due to the impact of the COVID-19 pandemic or otherwise, there may be delays in our ability to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates, any of which in turn could substantially harm our business

We have relied, and plan to continue to rely, upon third parties such as contract research organizations ("CROs") and hospitals to conduct, monitor, and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and manage and control only some aspects of their activities. In addition, third parties may not prioritize our clinical trials relative to those of other customers due to resource or other constraints as a result of the COVID-19 pandemic. Due to the continued impact of the COVID-19 pandemic or otherwise, we may experience enrollment at a slower pace at certain of our clinical trial sites than initially anticipated. Further, our clinical trial sites may be required to suspend enrollment due to travel restrictions, workplace safety concerns, quarantine, facility closures, and other governmental restrictions. As a result, results from our clinical trials may be delayed, which in turn would have a material adverse impact on our clinical trial plans and timelines and impair our ability to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates. This in turn would substantially harm our business and operations.

We expect to rely on third parties to manufacture our clinical product supplies and to produce and process our product candidates, if approved. The commercialization of any of our product candidates could be stopped, delayed, or made less profitable if those third parties are unable to provide us with sufficient quantities of drug product, or to do so at acceptable quality levels or prices due to the COVID-19 pandemic or otherwise.

We currently rely on outside vendors to manufacture our clinical supplies of our product candidates and plans to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved. The COVID-19 pandemic has placed a significant strain on the pharmaceutical industry, manufacturers of clinical supplies, healthcare-related supplies and resources, and the healthcare-related manufacturing sector in general. The impact of the COVID-19 pandemic has exacerbated the risks to which we are subject due to our reliance on third-party manufacturers. For example, we may be unable to identify manufacturers on acceptable terms or at all or third-party manufacturers may not be able to execute our manufacturing procedures appropriately or may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints, the impact of the COVID-19 pandemic, or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the

supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Due to our limited number of employees, our operations could be significantly and disproportionately impacted if any of our personnel were to test positive for COVID-19.

We are a small company with a limited number of employees performing multiple tasks each. We are also highly dependent on David J. Arthur, our president and chief executive officer, the loss of whose services may adversely impact the achievement of our objectives. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. Additionally, this shortage of highly qualified personnel is particularly acute in the area where our headquarters are located. If any of our personnel were to test positive for COVID-19, it would likely significantly impair our operations. The loss of services of any of our personnel, including Mr. Arthur, particularly for an extended period due to COVID-19 or otherwise, would likely impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

We may face business disruption and related risks resulting from President Trump's recent invocation of the Defense Production Act, either of which could have a material adverse effect on our business.

In response to the COVID-19 pandemic, President Trump invoked the Defense Production Act, codified at 50 U.S.C. §§ 4501 et seq. (the "Defense Production Act"). Pursuant to the, Defense Production Act the federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense. While we have not experienced any significant impact on our business as a result of such actions, we continue to assess the potential impact COVID-19 and the invocation of the Defense Production Act may have on our ability to effectively conduct our commercialization efforts and development programs and otherwise conduct our business operations as planned. There can be no assurance that we will not be further impacted by the COVID-19 pandemic or by any action taken by the federal government under the Defense Production Act, including downturns in business sentiment generally or in our industry and business in particular.



Safe Harbor Statement

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statement in this presentation that is not a historical fact is a forward-looking statement. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. Examples of such statements include, but are not limited to: statements relating to the overall ability of epigenetic regulator drugs to correct gene changes in disease, including how modulation of LSD1 may increase responsiveness to checkpoint inhibition; the commercial or market opportunity and expansion for each therapeutic option, including the availability and value of a pediatric priority review youcher for in-clinic treatments and potential for accelerated approval; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials and regulatory submissions; Seclidemstat's impact in Ewing sarcoma and as a potential new and less-toxic treatment; expected dose escalation and dose expansion; expected cohort readouts; expected therapeutic options for SP-2577 and related effects and projected efficacy, including SP-2577's ability to inhibit LSD1; the potential for SP-2577 to differentiate itself from competing LSD1-inhibitors; timing of development and future milestones, including for each of SP-2577's indications; the nature, strategy and focus of Salarius; and the development, expected timeline and commercial potential of any of our product candidates or our competitors. We may not actually achieve the plans, carry out the intentions or meet the expectations, objectives or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation: risks and uncertainties associated with the availability of sufficient resources to meet our business objectives and operational requirements, including amounts remaining available under the CPRIT grant; the risk that we may not obtain or maintain sufficient levels of reimbursement for our clinical trials and product development, including from CPRIT; the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; the fact that the results of earlier studies and trials may not be predictive of future clinical trial results; our quarter-end closing procedures and finalization of our quarterly financial results; the sufficiency of our intellectual property protections; risks related to the drug development and the regulatory approval process; other legal and regulatory uncertainties; the market price of our common stock and our ability to maintain the listing of our common stock on Nasdag; the impact of the ongoing COVID-19 pandemic and the success of any measures we have taken or may take in response thereto; and the impact of competitive products and technological changes. We disclaim any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. You should review additional disclosures we make in our filings with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, and Current Reports on Form 8-K. You may access these documents for no charge at http://www.sec.gov. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.



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Risk Factors

Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in our SEC filings. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our securities to decline and could cause you to lose all or part of your investment. Risks include but are not limited to:

- The approach Salarius is taking to discover and develop novel oncology therapeutics using epigenetic enzymes to moderate transcription factors and thereby
 control abnormal protein expression is unproven and may never lead to marketable products.
- Salarius' therapeutic product candidates are based on a relatively novel technology, which makes it difficult to predict the timing and cost of development and of subsequently obtaining regulatory approval, if at all.
- Salarius' product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.
- Some of Salarius' product candidates may produce results in pre-clinical or clinical settings for indications other than those for which Salarius contemplates
 conducting development and seeking FDA approval, and Salarius cannot give any assurance that it will generate data for any of its product candidates sufficient
 to receive regulatory approval in its planned indications, which will be required before they can be commercialized.
- Salarius may find it difficult to enroll patients in its clinical trials given the limited number of patients who have the diseases for which its product candidates are being studied. Difficulty in enrolling patients is a common hurdle faced by early stage biotechnology companies and could, and often does, delay or prevent clinical trials of product candidates.
- · Salarius has never generated any revenue from product sales and may never generate revenue or be profitable.
- · Raising additional capital may cause dilution to Salarius' stockholders, restrict its operations, or require Salarius to relinquish rights.
- · Salarius may seek breakthrough therapy designation by the FDA for one or more of its product candidates, but it might not receive such designation.
- A potential breakthrough therapy designation by the FDA for Salarius' product candidates may not lead to a faster development or regulatory review or approval
 process, and it does not increase the likelihood that Salarius' product candidates will receive marketing approval.



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Mission Statement



Developing treatments for patients that need them the most



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Corporate Overview



Drugs that regulate gene expression ("epigenetics") have shown clinical efficacy plus immuno-oncology potential



Lead candidate, seclidemstat is a novel, oral, reversible LSD1 inhibitor that regulates gene expression and is currently in Phase 1/2 Ewing sarcoma and Phase 1/2 solid tumor clinical trials



Seclidemstat FDA designations for Ewing sarcoma:

(1) Rare Pediatric Disease Designation, (2) Orphan Drug Designation, and (3) Fast Track Approval



Non-Dilutive funding in addition to low monthly burn rate

- Up to an aggregate of \$18.7M¹ from Cancer Prevention Research Institute of Texas (CPRIT)
- Financial support from the National Pediatric Cancer Foundation



Market expansion in targeted cancers with LSD1 sensitive mutations and immunotherapy (checkpoint inhibitor combos)

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As of June 30, 2020, the Company had received \$9.6M from CPRIT and there is up to \$9.1M available subject to certain requirements and spending restrictions.

Seasoned Leadership Team



David J. Arthur
Chief Executive Officer

















Board of Directors

	David Arthur, MBA	Jonathan Lieber, MBA	Tess Burleson, CPA	Paul Lammers, MD MSc	Bruce McCreedy, PhD	William McVicar, PhD	Arnold Hanish, CPA
	Salarius Pharmaceuticals	Danforth Advisors	Translational Genomics Research	Triumvira Immunologics	Precision BioSciences	Flex Pharma	Omeros Corporation
		Histogenics	Institute	Merck Serono	Triangle	Sepracor	Eli Lilly
0					Pharmaceuticals	Novartis	,



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Recent and Anticipated Milestones

	Development Milestones	Timing
②	Rare Pediatric Disease and Orphan Status Designation	2017
\bigcirc	FDA Fast Track Status	2H 2019
②	Phase 1 Ewing data (pediatric subcommittee Oncologic Drug Advisory Committee)	1H 2020
②	Presented at pediatric subcommittee of the Oncologic Drug Advisory Committee	1H 2020
	Additional Phase 1 Ewing data	2H 2020
	Initiate potential hematologic trial	2H 2020
	Initiate potential immunotherapy combo trial	2H 2020
	CPRIT Distribution	2H 2020
	Initiate Ewing-related sarcoma expansion	1H 2021
	Phase 1 Ewing early efficacy data readouts begin	1H 2021
	Phase 1 AST early efficacy data readouts begin	1H 2021
	Potential for Phase 1/2 Ewing and Ewing-related sarcoma readouts	2H 2021
,	Initiate potential Phase 1/2 targeted mutation solid tumor study	2H 2021



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Development Pipeline

	Indication	Preclinical	Phase 1	Phase 2 ¹	Status
	Ewing Sarcoma	Dose Escalation a	and Expansion		Phase 1/Phase 2 enrolling up to 50 patients
Seclidemstat	Advanced Solid Tumors	Dose Escalation a Expansion ²	ind		Phase 1/Phase 2 enrolling up to 50 patients
Seclide	Immunotherapy	In vitro and In vivo studies ongoing			Identifying combinations and indications for clinical trials
	Hematologic cancers	In vitro and In vivo studies ongoing			Identifying combinations and indication for clinical trials
	Identifying opportunities in select tumor mutations				

- 1. Expanded Phase 2 in Ewing sarcoma could potentially be a registration study with improvements in response or duration of response compared to the existing standard of care and FDA's agreement 2. Open to all non-Ewing sarcoma solid tumor patients except for primary CNS tumors, potential to enrich for patients with sensitive mutations and prostate cancer that can be monitored with prostate specific antigen

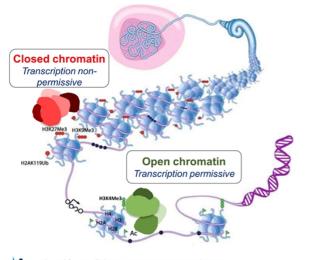




Seclidemstat Overview

Epigenetic enzymes are attractive targets for cancer therapy

Epigenetic modifying enzymes affect gene expression by manipulating the chromatin structure



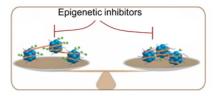
Dysregulated epigenetic enzymes can disrupt the transcriptional balance and lead to cancer development

Tumor growth genes

Dysregulated epigenetic enzyme

Tumor suppressive genes

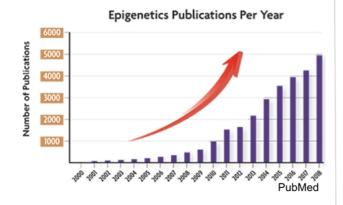
Drugs that correct dysregulated epigenetic enzymes can help treat cancer by restoring to a balanced transcriptional state



Adapted from Holliday, H. Breast Cancer Research 2018 © 2020 Salarius Pharmaceuticals, Inc. Adapted from Marcin et al. Biomed Intel 2018.

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Epigenetic Research is Gaining Momentum and Epigenetic Focused Biotechs are Increasing in Valuation



Novel epigenetic drugs with clinical proof of concept support billion-dollar valuations



EZH2 inhibitor (tazemetostat)

Approved in epithelioid sarcoma – monotherapy Approved for R/R follicular lymphoma – monotherapy **Market Cap:** ~\$1.5B¹



BET inhibitor (CPI-0610)

Positive Phase 2 data in combination with existing standard of care in myelofibrosis

Market Cap: ~\$1.3B¹

Other clinical companies include: GSK, Zenith Epigenetics, Resverlogix, 4SC, Viracta, Syndax



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¹ As of 07/14/2020; not intended to be indicative of Company's current or potential market cap.

LSD1 - A Validated Target For Cancer Therapy

Lysine Specific Demethylase 1 (LSD1) affects gene expression through enzymatic activity and scaffolding properties (protein-protein interactions), making it an attractive target for solid tumors and hematological cancers.

LSD1 in No	ormal Cells and Cancer Cells ¹
Normal Cells	LSD1 is necessary for stem cell maintenance and cell development processes (e.g., blood cells)
Cancer Cells	LSD1 is over expressed LSD1 acts incorrectly to silence or activate genes leading to disease progression Validated target: LSD1 CRISPR deletion often detrimental to cancer cells



Seclidemstat (SP-2577) reversibly inhibits LSD1

- Reverses incorrect gene expression, killing or preventing the growth of cancer cells
- Inhibits both the enzymatic and scaffolding activity



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¹Majello,B. Cancers 2019. ²Appendix B

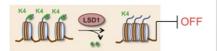
More Comprehensive Inhibition of LSD1 Positively Impacts Therapeutic Activity

Degree of LSD1 inhibition



Enzymatic activity – Demethylation

Impact: Moderately alter gene expression



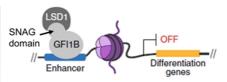






Partial scaffolding* inhibition of LSD1 – protein interaction

Impact: Alter gene expression in cancers (AML, SCLC) driven by SNAG domain proteins (e.g. GFI1B)





*scaffolding properties - protein to protein interactions





Broader scaffolding inhibition of LSD1 – protein interaction

Impact: Potential efficacy in broader range of cancer types, destabilize LSD1 and complexes





Differential activity



Reduces LSD1 expression





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LSD1 Competitive Landscape Highlights Seclidemstat's Differentiation

	Company	Drug Name	Binding Mechanism	Indications and Phase
	Salarius PHARMACEUTICALS	SP-2577 (Seclidemstat)	Reversible	Ewing sarcoma (Ph1/2), Advanced Solid Tumors (Ph1/2)
clinic1	ORYZON	ORY-1001 (RG6016)	Irreversible	AML combo (Ph2b), SCLC combo (Ph2a)
ln c	Celgene	CC-90011	Reversible	Non-Hodgkin's lymphoma and AST (Ph1), SCLC combo (Ph1b), IO combo (Phase 2)
	Imago 🎳	IMG-7289	Irreversible	AML and myelodysplastic syndrome (Ph1/2a completed), myelofibrosis (Ph2b), essential thrombocythemia (Ph2a)
				¹ Clinicaltrials.gov

Seclidemstat's
differentiated binding
mechanism (reversibility)
and binding location
shows potential
increased therapeutic
activity and safety*

			¹Clinicaltrials.gov
BE/(CTICA	BEA-17	Reversible	Glioblastoma
RASNA THERAPEUTICS	RASP-201	Reversible	AML
Hanmi	HM9XXX series	Reversible	AML and SCLC

Preclinical research is shifting to develop reversible LSD1 inhibitors

²Not an exhaustive list of companies in preclinical stage



GlaxoSmithKline and Incyte previously had clinical LSD1 programs (irreversible) that have since been terminated

*Being studied in our ongoing Phase 1 trials



Ewing Sarcoma - Unmet Need Represents a Meaningful Product Opportunity

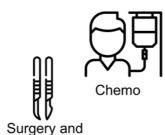
Diagnosis



~500 patients diagnosed each year Median age of diagnosis ~15 years

- 75% localized¹
- 25% with metastasis¹

Standard of Care



Amputations



Radiation

 About 40% of patients are refractory or relapse²

² Van Mater, et al. Oncotargets (2019)

- 70-90% 5-year mortality rate²
- No standardized 2nd line treatment

Salarius' Vision

An effective, non-toxic, oral treatment option:

- Accelerated US approval
- Rapid market uptake
- \$200M+ Global Sales³ (est.)
- Possible Priority Review Voucher of \$80M - \$150M







³ Represents longer term vision and does not represent estimate of future performance, financial or otherwise. There is no assurance that we will achieve our longer-term vision.

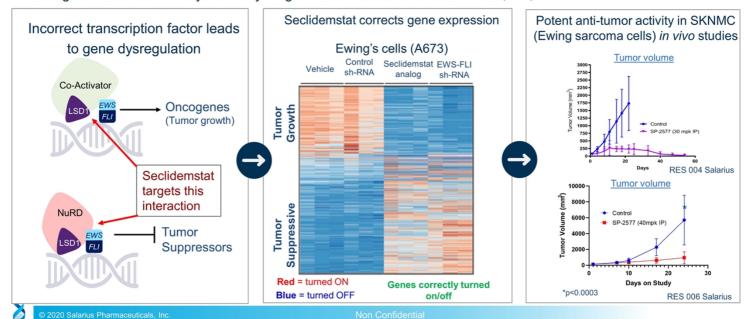


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Targeting The Root Cause Of Ewing Sarcoma Via LSD1 Inhibition

Ewing sarcoma is driven by an easily diagnosed chromosomal translocation, i.e., EWS-FLI



Sankar et al. Clinical cancer research 20.17 (2014)

Ewing Sarcoma Phase 1/2: Safety and Efficacy Data in 2020

Open-label dose escalation / dose expansion trial design

Dose escalation (ongoing)

- Dose escalation in cohort 6
- Maximum Tolerated Dose (MTD) expected in 2H2020

Dose expansion (after MTD is established)

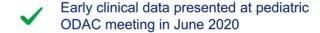
- ~20 patients at Recommended Phase 2 Dose
- Safety and early efficacy data in 1H2021

Primary objective: Safety, PK

Secondary objectives: Anti-tumor assessment Exploratory: Hemoglobin F, cfDNA, CTCs









Salarius Plans To Expand Ewing Sarcoma Trial To Include **Ewing-related Sarcomas**

- ➤ Preclinical activity and early clinical observations in sarcomas driven by FET family* gene rearrangements suggest seclidemstat may be a potential treatment option
 - Ongoing Ewing sarcoma trial amended to include these Ewing-related sarcomas at recommended phase 2 dose (RP2D)



Myxoid liposarcoma

EWS

CHOF

Desmoplastic Small Round cell tumor

Clear cell sarcoma1







Cohort 1: Ewing sarcoma expansion

☐ 20 evaluable Ewing sarcoma patients with known EWSR1 translocation at RP2D

Cohort 2: Ewing-related sarcoma expansion

- ☐ Myxoid liposarcoma (7-10 evaluable patients)
- ☐ Desmoplastic small round cell tumor (7-10 evaluable patients)
- Other sarcomas that also share similar chromosomal translocations (EWS-, FUS-, TAF15-) to Ewing sarcoma (up to 10 evaluable patients)



¹Clear cell sarcoma represents an example of other sarcomas eligible for enrollment

Phase 1a Ewing Safety Data And Preliminary Drug Activity Observed In Patient's Target Lesions As Assessed By Investigator

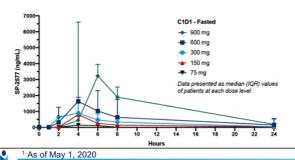
Early dose escalation results

Patients enrolled¹: 21 patients

- No treatment related deaths or study discontinuations due to treatment-related adverse events
- Dose-limiting toxicities have not prevented dose escalation

Pharmacokinetics:

- At dose levels 900 mg BID and above cohorts achieving drug levels of preclinical efficacious concentrations
- 5-8 hour half-life supports BID dosing

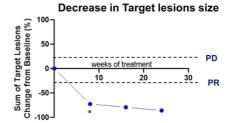


Preliminary drug activity in target lesions of refractory Ewing's patient

- Feb 2016: 30 year-old male diagnosed and treated with standard VDC/IE chemotherapy
- · July 2017: Presented with bone lesion and treated with standard I/T chemotherapy
- Feb 2019: External beam radiation treatment
- · Sep 2019: Enrolled in SP-2577 study at 600 mg BID dose cohort.

Prospectively defined target lesions decreased 86% in size after 6 months of treatment

- Partial Response (PR) of target lesions
- At cycle 2 non-target lesions increased resulting in overall assessment of Progressive Disease (PD) per RECIST 1.1.
- Patient continued treatment for additional 4 cycles (total of 6 cycles) due to response in target lesions and clinical benefit as determined by Investigator.



* PD in non-target lesions at 8 weeks, patient continued therapy

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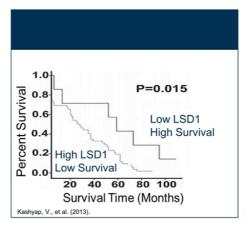


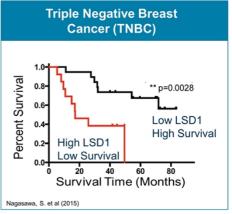
LSD1 Overexpression Increases With Disease Progression And Correlates With Poor Patient Prognosis – Seclidemstat Reduces LSD1 Activity



Increased LSD1 expression correlates with solid tumor progression

- High LSD1 expression in ~30% of primary prostate tumors, but >90% of advanced castration resistant prostate cancer¹
- LSD1 expression associated with shorter survival in Triple Negative Breast cancer





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Ongoing Phase 1 Advanced Solid Tumor Study sites: Honor Health, Phoenix AZ and Sarcoma Oncology Center, Santa Monica CA

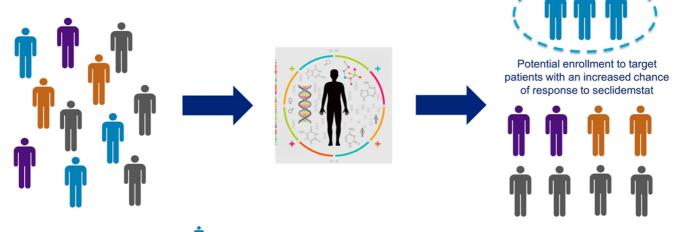
¹ Sehrawat, A. et. al., 2018



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Increasing Probability Of Success Via Identification Of Known Sensitizing Mutations

Genetic screens (e.g., Foundation Medicine) can help identify patients with an increased chance of response to seclidemstat



Represents patient with potential sensitizing mutations identified by Salarius

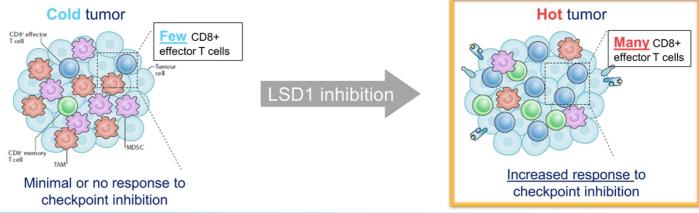
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LSD1 Inhibition Turns Cold Tumors Hot And Increases Efficacy Of Checkpoint Inhibitors

Sensitizing cancers resistant to checkpoint inhibitors (CPI) increases patients available for treatment

- ~\$15B CPI market¹ with ~70% patients² resistant to CI treatment (cold tumors)
- LSD1 inhibition turns cold tumors hot by increasing CD8+ effector T cells within the tumor
- · Expands CPI market into patients currently resistant to CPI treatment



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GlobalData

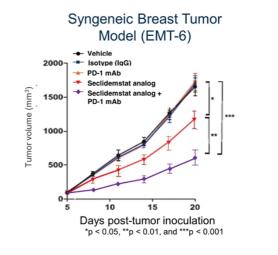
2. Seliger, B. Front in Immun (2019)

LSD1 Inhibition Sensitizes Triple Negative Breast Cancer to Checkpoint Blockade *in vivo*

Oncogene

Inhibition of histone lysine-specific demethylase 1 elicits breast tumor immunity and enhances antitumor efficacy of immune checkpoint blockade

- LSD1 inhibition (Seclidemstat analog)
 drives increased immune cell infiltration,
 and sensitizes resistant tumors to
 checkpoint inhibition
- "Cold" tumors turn "Hot" and then respond to checkpoint inhibition
- Increased response by ~65%



Qin, Ye, et al. Oncogene (2018).

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Combination of Possibilities Presents Significant Market Opportunity for Seclidemstat

SPEED TO MARKET





Potential for accelerated approval, priority review

\$80M-\$150M

Possible Pediatric Priority Review Voucher (est.)

EXPANDING INTO LARGER MARKETS

ADVANCED SOLID TUMORS

Ongoing work to identify SELECT TUMOR MUTATIONS

that may increase patient response to LSD1 inhibition (e.g. SWI/SNF)



Market Potential in Solid Tumors 2,3,4,5,6

About 25% of solid tumors (e.g., breast, ovarian, prostate, lung) may have mutations that sensitize to seclidemstat6

POTENTIAL TO ENTER INTO IMMUNOTHERAPY and **HEMATOLOGIC CANCERS**

Sensitizing resistant cancers to checkpoint Inhibitors

\$1B+ Market Potential⁷

Hematologic cancers with clinical evidence for LSD1i

\$1B+ Market Potential⁸

Citations in Appendix A

Financial Position & Capitalization -- Use of Proceeds

Capitalization as of June 30, 2020	
Common Shares Outstanding	14.6M
Warrants (weighted average exercise price \$1.45)	9.3M
Options (weighted average exercise price \$17.51)	0.3M
Fully Diluted Shares	24.2M

Cash & Cash Equivalents: \$7.2M as of June 30, 2020

Use of Proceeds

- Expansion of Ewing sarcoma trial to other sarcomas of interest
- 2) Provide additional runway to existing clinical programs



Salarius Investment Opportunity: Clinical Stage Biotech With Several Value-driving Inflection Points Occurring In 2020/2021



Lead compound is in the growing epigenetic therapy space

· Attractive price for investors interested in this growing therapeutic area



Extensive non-dilutive funding coupled with low quarterly burn rate

Up to \$18.7M¹ from CPRIT
 Financial support from NPCF



Recipient of FDA designations that facilitates rapid product development

Orphan Drug Designation
 Rare Pediatric Disease Designation
 Fast Track Designation

Salarius is positioned for a newsworthy 2020 and 2021:

Two ongoing clinical trials are expected to readout safety, pharmacokinetic, and early efficacy data. Potential to initiate additional trials.



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As of June 30, 2020, the Company had received \$9.6M from CPRIT and there is up to \$9.1M available subject to certain requirements and spending restrictions.



Appendix A: Additional Sources

- · Combination of Possibilities Presents Significant Market Opportunity for Seclidemstat
 - 1 Represents longer term vision and does not represent estimate of future performance, financial or otherwise. There is no assurance that we will achieve our longer term vision.
 - 2 Cancer of the Ovary Cancer Stat Facts, The National Cancer Institute: Surveillance, Epidemiology and End Results Program https://seer.cancer.gov/statfacts/html/ovary.html.
 - ³ GlobalData: Prostate Cancer: Global Drug Forecast and Market Analysis to 2028
 - ⁴ GlobalData and Epidemiology Market Size Database, TNBC
 - ⁵ GlobalData: Opportunity Analyzer: Ovarian Cancer Opportunity Analysis and Forecast to 2025
 - ⁶ Morel, D., et al. Ann of Oncology 2017
 - 7 https://www.forbes.com/sites/greatspeculations/2019/03/12/how-much-can-mercks-share-price-grow-if-keytruda-gets-10-share-of-oncology-drug-market/#77edba677e18
 - ⁸ Hematological Malignancies. Apr 2020. Brand Essence Market Research.



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Appendix B: US Intellectual Property Portfolio

Composition of matter: #8,987,335Composition of matter: #9,266,838

Methods of Use: #9,642,857Methods of Use: #9,555,024



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