

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): August 12, 2019

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
(IRS Employer Identification No.)

2450 Holcombe Blvd.
Suite J-608
Houston, TX
(Address of principal executive offices)

77021
(Zip Code)

(346) 772-0346
(Registrant's telephone number, including area code)
N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- 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))

Title of each class
Common Stock, \$0.0001 par value

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

Trading symbol(s)
SLRX

Name of each exchange on which registered
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 x

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. x

Item 2.02 Regulation FD Disclosure.

On August 12, 2019, Salius Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the issuance of an open letter to its stockholders from its chief executive officer (the “Stockholder Letter”). A copy of the press release is furnished as Exhibit 99.1 hereto.

The Company is also furnishing its corporate presentation (the “Presentation”) as Exhibit 99.2 hereto. The Company does not undertake to update the Presentation.

The Stockholder Letter and the Presentation will also be made available on the Investors – Overview page of the Company’s website at <http://investors.saliuspharma.com/>.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press release issued by the Registrant on August 12, 2019. |
| 99.2 | Corporate Presentation of the Registrant for Q3 2019. |

SIGNATURES

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.

Dated: August 12, 2019

Salaris Pharmaceuticals, Inc.

By:

/s/ David J. Arthur

David J. Arthur
President and Chief Executive Officer



Salarius Pharmaceuticals CEO Issues Letter to Stockholders

Houston, TX – August 12, 2019 – [Salarius Pharmaceuticals, Inc.](#) (Nasdaq: SLRX), a clinical-stage oncology company targeting the epigenetic causes of cancers, today announced that its chief executive officer, David Arthur, issued an open letter to Salarius' stockholders following the completion of the reverse merger with Flex Pharma, Inc. The following letter can also be viewed on Salarius' website.

Dear Stockholder,

We are thrilled to have completed the merger with Flex Pharma and to have begun trading on Nasdaq with the new trading symbol "SLRX". This represents the culmination of many years of hard work, dedication, and innovation from talented people, and we are proud of what we have accomplished.

Following the reverse merger, Salarius' stockholder base is now comprised of a combination of former Flex Pharma stockholders, former unit holders of Salarius Pharmaceuticals, LLC, and new stockholders. The purpose of this letter is to provide each of you with an overview and update on Salarius Pharmaceuticals, Inc. and our plan for building stockholder value by advancing clinical programs.

Salarius' development trajectory is on course and we look forward to your support as we work toward developing novel treatments for patients who need them the most. We believe in our science, vision and clinical programs that are poised to generate data validating our approach. Additionally, prior to entering into the merger agreement with Flex Pharma, our technology, pipeline, clinical plan, market opportunity, finances, and management team were reviewed carefully by Flex Pharma. Flex Pharma selected Salarius based on due diligence and discussions with nearly 40 other companies, which we believe provides substantial third-party validation for our business.

In short, Salarius is a cancer-focused biotechnology company developing treatments for patients who need them the most. Today, that includes active clinical development programs dedicated to delivering new therapeutic options for:

- Patients with Ewing Sarcoma, a rare and devastating bone and soft-tissue cancer that mostly afflicts children and young adults for which no approved targeted therapies are currently available. Unfortunately, the standard of care treatment for these children and young adults currently is adult chemotherapy, radiation and often disfiguring surgeries.
- Patients with advanced solid tumors, such as prostate, breast, and ovarian cancers who have not responded to or are no longer responding to standard of care treatments and are seeking new potential treatments.

Our lead drug candidate or potential medicine, Seclidemstat, is an oral tablet with a targeted, disease-specific mechanism of action, unlike toxic chemotherapy.

Our technology targets the epigenetic causes of cancer. Epigenetics is the study of the regulatory system that controls how genes are turned “on” or “off.” In certain cancers, the proteins that regulate gene expression become dysregulated and incorrectly turn genes “on” or “off,” which in some cases leads to cancer progression. Drugs that are able to safely modify the activity of these epigenetic regulators may correct the gene changes that are driving the disease. The field of epigenetics is maturing, and with a differentiated drug candidate in two clinical studies, Salarius has the potential to become a leader in this exciting area of cancer research.

The Food and Drug Administration (FDA) has already granted our lead drug candidate, Seclidemstat, both Orphan Drug and Rare Pediatric Disease designations, conferring certain regulatory benefits and commercial advantages upon a potential FDA approval. If proven efficacious with a benefit-risk profile that the FDA judges to be positive and supportive of approval, Seclidemstat could qualify to receive a pediatric priority review voucher (PRV), which the FDA awards to companies developing a drug or biologic that targets a rare pediatric disease. If received, this voucher adds significant value to our Seclidemstat program. PRVs can be sold to other qualifying companies and based on 2017-2018 selling prices, a PRV has a value ranging between \$80 million and \$150 million.

Our Ewing Sarcoma program is progressing in a Phase 1 clinical trial that is currently in the dose escalation phase, and we expect to establish the maximum tolerable dose (MTD) in early-2020. We then expect to commence dose expansion with the potential for reporting early cohort data later in 2020.

We are also developing Seclidemstat for adults with advanced solid tumor cancers. We recently began enrolling a Phase 1 dose escalation/dose expansion study in advanced solid tumors, including but not limited to, breast, ovarian and prostate cancer patients. Early cohort data readouts are also expected in 2020.

Importantly, in 2016, Salarius was granted a \$18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), of which approximately \$11.8 million remains available to Salarius. This funding, which does not dilute investor equity holdings, has enabled us to move our programs forward. In addition, the National Pediatric Cancer Foundation (NPCF) provides financial support funding our Ewing sarcoma clinical trial. This NPCF funding also does not dilute investor equity holdings.

We are committed to advancing Seclidemstat toward potential FDA and global approval. Our team of scientists, clinicians, and other professionals, as well as our Board of Directors and Scientific Advisors are dedicated to this effort and to the opportunity to improve patients’ lives.



In addition, Salariaus' executive officers and Board members, and certain executive officers, directors and stockholders of Flex Pharma (prior to the merger), agreed to a 90-day restriction on sales by them of the company's shares. We see great potential for Seclidemstat, for our clinical pipeline, and for our ability meet the unmet medical needs of patients.

In terms of upcoming financial disclosures, we plan to file a Form 8-K/A within the next few months that will contain certain interim and pro forma financial information relating to the merger of the two companies. Going forward, we will report our quarterly and year-end financial results, as required, on a typical filing schedule for public companies, including our results for the third quarter ended September 30, 2019.

We believe stockholder value is created by reporting clinical data showing patient benefit in response to Seclidemstat. To that end, our timeline for releasing clinical data and reaching possible inflection points is largely unchanged. In June 2019, Salariaus was a private company executing a clinical plan to potentially report early patient cohort data in 2020. Two months later, we are a public company listed on Nasdaq executing that same clinical plan to potentially report early patient cohort data in 2020.

Our top priority is the continued execution of our clinical trials and as such, patient enrollment and efficient clinical operations remain our top focus. We look forward to providing updates on our progress and we invite you to visit our website at salariauspharma.com for more information.

We thank you for your current support and for your continued support as we strive to deliver maximum value for you, our stockholder, and deliver potential new medicines for the many patients and their families fighting cancer.

Best regards,

David Arthur
Chief Executive Officer

XXX

About Salariaus Pharmaceuticals

Salariaus Pharmaceuticals, LLC is a clinical-stage oncology company targeting the epigenetic causes of cancers and is developing treatments for patients that need them the most. The company's lead candidate, Seclidemstat, is currently in clinical development for treating Ewing sarcoma, for which it has Orphan Drug designation and Rare Pediatric Disease Designation by

the U.S. Food and Drug Administration. Salarium believes that Seclidemstat is one of only two reversible inhibitors of the epigenetic modulator LSD1 currently in human trials, and that it could have potential for improved safety and efficacy compared to other LSD1-targeted therapies. Salarium is also developing Seclidemstat for a number of cancers with high unmet medical need, with an ongoing clinical study in Ewing sarcoma and a clinical study in advanced solid tumors, including prostate, breast and ovarian cancers. Salarium receives financial support from the National Pediatric Cancer Foundation to advance the Ewing sarcoma clinical program and is also the recipient of an \$18.7 million Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit salariumpharma.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to: the potential for Seclidemstat to target the epigenetic dysregulation underlying Ewing sarcoma and advanced solid tumors including, but not limited to, prostate, breast, and ovarian cancers; expected timing and results of clinical studies; Salarium’s development trajectory; third-party validation for Salarium’s business; changes in the field of epigenetics and Salarium’s potential in such field; the likelihood of Seclidemstat qualifying to receive a pediatric priority review voucher (PRV) and the potential value of such PRV; Seclidemstat’s FDA and global approval and expected benefits and advantages upon obtaining FDA approval; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. Salarium may not actually achieve the plans, carry out the intentions or meet the expectations or objectives disclosed in the forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements are subject to risks and uncertainties which could cause actual results and performance to differ materially from those discussed in the forward-looking statements. These risks and uncertainties include, but are not limited to, the following: the ability of the company to raise additional capital to meet the company’s business operational needs and to achieve its business objectives and strategy; the company’s ability to project future capital needs and cash utilization; future clinical trial results; that the results of studies and clinical trials may not be predictive of future clinical trial results; the sufficiency of Salarium’s intellectual property protection; risks related to the drug development and the regulatory approval process; and the competitive landscape and other industry-related risks. Salarium disclaims 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.

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Company Overview

Q3 2019



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 commercial or market opportunity and expansion; the adequacy of Salarius' capital to support its future operations and its ability to successfully initiate and complete clinical trials and regulatory submissions; expected dose escalation and dose expansion; number of additional clinical sites; expected cohort readouts; expected therapeutic options for SP-2577 and related effects; timing of development and future milestones; the nature, strategy and focus of Salarius; future economic conditions and performance; and the development, expected timeline and commercial potential of any product candidates of Salarius. Salarius may not actually achieve the plans, carry out the intentions or meet the expectations 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 of Salarius 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 fact that the results of earlier studies and trials may not be predictive of future clinical trial results; the ability to protect Salarius' intellectual property rights; risks related to the drug development and the regulatory approval process; and the impact of competitive products and technological changes. Salarius disclaims 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 and our Annual Report on Form 10-K. You may access these documents for no charge at <http://www.sec.gov>.

A registration statement on Form S-3 of Flex Pharma, Inc. has been filed with the Securities and Exchange Commission and declared effective. The offering of these securities will be made only by means of a written prospectus supplement and base prospectus forming part of the effective registration statement relating to the shares. Copies of the prospectus for this offering may be obtained, when available, by contacting Oppenheimer & Co. Inc., 85 Broad Street, 26 Floor, New York, NY 10004, Attn: Syndicate Prospectus Department, by calling (212) 667-8563, or by email to EquityProspectus@opco.com.

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.



Investor Highlights: Salaris Pharmaceuticals is an Epigenetic Focused Clinical-stage Oncology Biotech Company

- 1 Salaris has a differentiated LSD1 inhibitor with expected human data in 2020**
 - Multi-company interest and clinical data validates LSD1 as a therapeutic target
- 2 Development strategy focused on Speed to Market and Market Expansion**
 - Speed to Market: Ewing sarcoma trial → Rare Pediatric Disease and Orphan Status Designation
 - Market Expansion: Advanced Solid Tumor trial → Hormonal cancers, sarcomas (\$1B+ markets)
- 3 Seasoned management team leading Salaris**
 - Experienced in product, clinical and early stage development
- 4 Lead clinical program funded by extensive non-dilutive capital**
 - \$18.7M CPRIT award and support from the National Pediatric Cancer Foundation
- 5 Opportune time to capitalize on growth potential**
 - Potential to expand into other indications of high value (including immunotherapy)
 - Relatively short timeline to pivotal inflection points



Seasoned Management Team



Lilly  **Boehringer Ingelheim**



Margaret Dugan, MD
Senior Medical Advisor

 **NOVARTIS**



Steve Horrigan, PhD
Chief Scientific Officer

 **Avalon Pharma**  **NOBLE**



Scott Jordan
Chief Financial Officer

 **Abbott**  **Healthios**



 **ILEX**  **REATA**
PHARMACEUTICALS



Daniela Y Santieste, PhD
Business Development Manager

 **TVL**  **Georgetown Tech**

Board of Directors

| | | | | | | |
|--|--|---|--|--|--|---|
| David Arthur, MBA Salius Pharmaceuticals | Jonathan Northrup, MBA Stingray Therapeutics | Tess Burleson, CPA Translational Genomics | Paul Lammers, MD MSc Triumvira | Bruce McCreedy, PhD Precision Medicine | William McVicar, PhD Flex Pharma | Arnold Hanis, CPA Omeros Corp |
|--|--|---|--|--|--|---|



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Saliarius' Clinical Pipeline

| | Indication | Preclinical | Phase 1 | Phase 2 | Status |
|--------------|-----------------------|-------------|---------|---------|---|
| Seclidemstat | Ewing Sarcoma | | | | <ul style="list-style-type: none">• Enrolling 30+ patients Phase 1 trial• Dose escalation• Early cohort data mid-2020 |
| | Advanced Solid Tumors | | | | <ul style="list-style-type: none">• Enrolling 30+ patients Phase 1 trial• Early cohort data mid-2020 |

Saliarius is positioned to achieve early cohort data readouts



Salariaus is Poised to Add to the Growing Epigenetic Wave

The epigenetic space has been increasing in activity since 2018

Preclinical



~\$1B deal (\$40M upfront) to advance a preclinical asset (lead optimization)

Clinical



Phase 1: LSD1; Ewing's and Solid Tumors



Phase 1: EZH2 and BET inhibitors; solid/heme



Phase 2: LSD1; AML and SCLC



Phase 2b: Raised \$40M to advance LSD1 program

Drug registration



Submitted an NDA for Epithelioid Sarcoma (1H2019) and has plans submit another for Follic Lymphoma (2H2019)

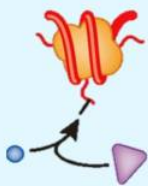


Salarius is an Epigenetic Focused Oncology Biotech Company

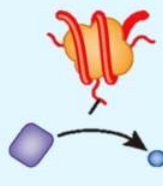
Epigenetics addresses how cells regulate gene expression through various chemical modifications

Epigenetic enzymes can be grouped into:

Writers



Erasers



Readers



Tarakhovsky Nat Immunol 2010

Examples:

DNMT1

DNA
methyltransferase 1

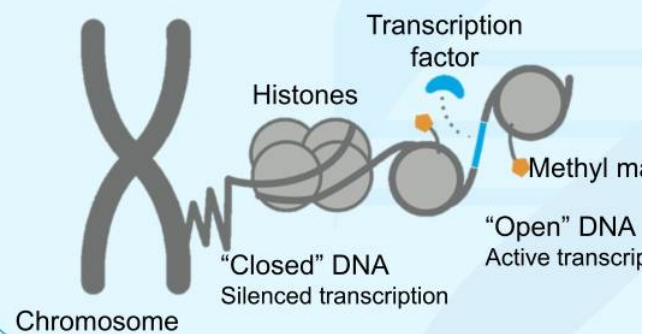
LSD1

Lysine specific
Demethylase 1 (LSD1)

BRD

Bromodomain
proteins

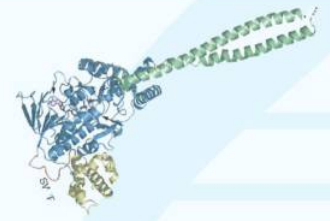
Salarius' lead compound inhibits LSD1, methyl mark eraser that influences "closing" "opening" of DNA to alter gene transcripti



LSD1 Is An Attractive Target For Cancer Therapy

- **Lysine Specific Demethylase 1 (LSD1)** is an epigenetic “eraser” that is a target of interest for solid tumors and hematological cancers

- LSD1 overexpression is often correlated with poor prognosis via regulation of pathways involved in:
 - Cell differentiation
 - Cell motility
 - Stem-like phenotype
 - Cell cycle
- LSD1 associates with over 60 gene regulatory proteins¹



LSD1 affects gene expression via enzymatic and scaffolding properties

Lead compound, **Secclidemstat** (SP-2577), comprehensively inhibits **LSD1**



LSD1 is a target of interest given its role in cancer progression



Review

Expanding the Role of the Histone Lysine-Specific Demethylase LSD1 in Cancer

Lysine-specific demethylase 1 (LSD1/KDM1A/AOF2/BHC110) is expressed and is an epigenetic drug target in chondrosarcoma, Ewing's sarcoma, osteosarcoma, and rhabdomyosarcoma^{☆☆☆}

Cell

LSD1 Is a Subunit of the NuRD Complex and Targets the Metastasis Programs in Breast Cancer

OPEN ACCESS Freely available online



Over-Expression of LSD1 Promotes Proliferation, Migration and Invasion in Non-Small Cell Lung Cancer



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Recent works demonstrate LSD demethylation independent activ

nature
chemical biology

ARTICLES

<https://doi.org/10.1038/s41589-019-0263-0>

CRISPR-suppressor scanning reveals a nonenzymatic role of LSD1 in AML

2019

DOI: 10.1002/ajb.27888

2019

RESEARCH ARTICLE

Pediatric
Blood &
Cancer

aspho

WILEY

Catalytic inhibition of KDM1A in Ewing sarcoma is insufficient as a therapeutic strategy

Cell Reports

2018

Enhancer Activation by Pharmacologic Displacement of LSD1 from GF11 Induces Differentiation in Acute Myeloid Leukemia

ARTICLES

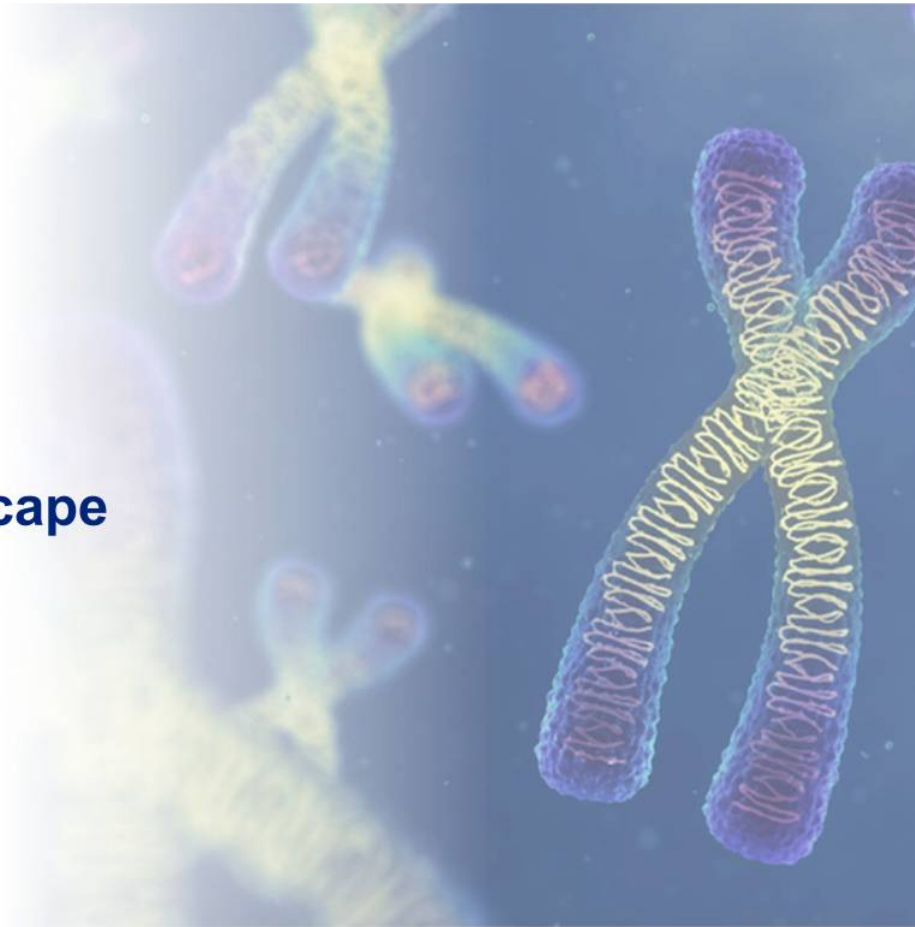
<https://doi.org/10.1016/j.celrep.2019.02.027>

nature
immunology

2019

Histone demethylase LSD1 is required for germinal center formation and BCL6-driven lymphomagenesis

Competitive Landscape and Differentiation

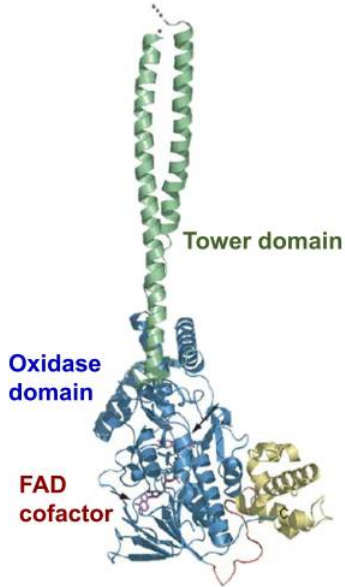


Seclidemstat is a Differentiated Inhibitor Addressing Areas of High Unmet Need Supported by Strong IP

- Seclidemstat (SP-2577) is a small molecule oral therapeutic differentiated by:
 - (1) Mechanism – reversible vs. irreversible
 - (2) Binding location – comprehensive inhibition of enzymatic and scaffolding properties
- Strategically positioned in indications of high unmet need w/ strong mechanistic rationale:
 - Ewing Sarcoma – Aggressive childhood bone cancer, no approved targeted treatments
 - Other Sarcomas – Share a similar biology to Ewing sarcoma
 - Late Stage Prostate/Breast/Ovarian and other cancers are upside
- Composition of matter patents allowed globally
 - US patent expires in 2032 exclusive of possible extensions



LSD1 Competitive Landscape Demonstrates Seclidemstatin Differentiation



| | Company | Drug Name | MoA | Indications and Phase |
|------------------------|---------------------------|-------------------|--------------|---|
| In clinic | Salariaus PHARMACEUTICALS | SP-2577 | Reversible | Ewing sarcoma (Ph1), Advanced Solid Tumors (Ph1) |
| | Incyte | INCB59872 | Irreversible | Advanced malignancies (AML, SCLC (Ph1/2), Ewing sarcoma (Ph1b)) |
| | ORYZON | ORY-1001 (RG6016) | Irreversible | AML (Ph2b), SCLC (Ph2a) |
| | Celgene | CC-90011 | Reversible | Non-Hodgkin's lymphoma and AML (Ph1), SCLC (Ph1) |
| | IMAGO | IMG-7289 | Irreversible | AML and myelodysplastic syndromes (Ph1/2a completed), myelofibrosis (Ph1) |
| Preclinic ¹ | BEACTICA | BEA-17 | Reversible | Glioblastoma |
| | RASNA THERAPEUTICS | RASP-201 | Reversible | AML |
| | Hanmi | HM9XXX series | Reversible | AML and SCLC |



Degree of LSD1 Inhibition Impacts Therapeutic Activity

Amount of LSD1 function inhibited

Enzymatic activity – Demethylation

Impact: Moderately alter gene expression



LSD1-- SNAG domain association

Impact: Alter gene expression – cancers driven by SNAG domain proteins (AML, SCLC)



Broader LSD1 – cofactor associations

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



- ✓ Differential activity
- ✓ Toxicology Profile



**Speed to Market:
Seclidemstat in Ewing
sarcoma**



Ewing Sarcoma – High Unmet Need in a Critical Population

- Devastating, painful disease that mostly affects children and adolescents
 - ~500 cases diagnosed annually in the US; median age of diagnosis is 15 years old¹
 - Current treatment causes debilitating short and long-term side effects
 - **70% of patients with relapsed/metastatic disease will succumb to the disease²**
- Salaris is developing an **effective and less-toxic treatment option**
 - Strong mechanistic rationale to target LSD1 -- cures in animal models
 - Potential FDA designations allow for accelerated approval opportunities
 - Orphan Status and Rare Pediatric Disease Designation granted
 - \$200M+ global market



Chemotherapy, Radiation
Disfiguring Surgeries

No standardized 2nd line
treatment



Possible Pediatric Prio
Review Voucher adds
additional ~\$100M of val
Seclidemstat

¹ Sarcoma Foundation: Ewing's Sarcoma from www.curesarcoma.org/patient-resources/sarcoma-subtypes/Ewings-sarcoma/

² Pishas, Kathleen I and Stephen L Lessnick. "Recent advances in targeted therapy for Ewing sarcoma" *F1000Research* vol. 5 F1000 Faculty Rev-2077. 25 Aug. 2016

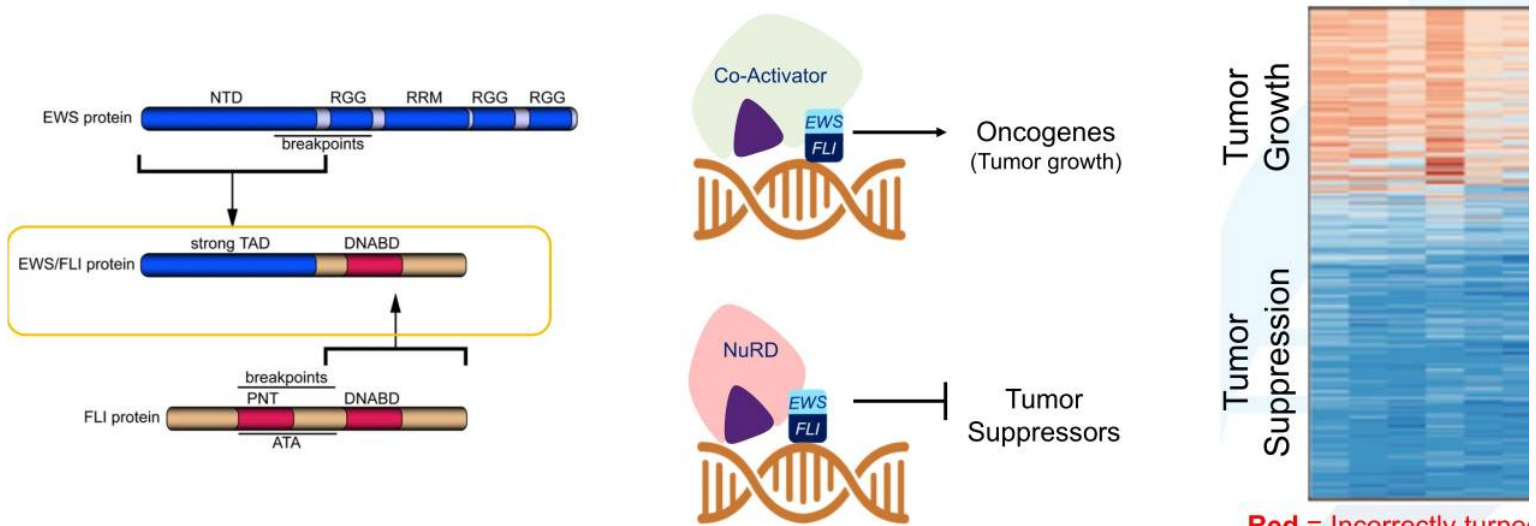


Therapeutic Opportunities In Ewing Sarcoma: EWS-FLI Inhibition Via LSD1 Targeting

Ewing sarcoma is driven by a chromosomal translocation

Aberrant transcription factor - gene dysregulation

Oncophenotype
Ewing cells (A673)

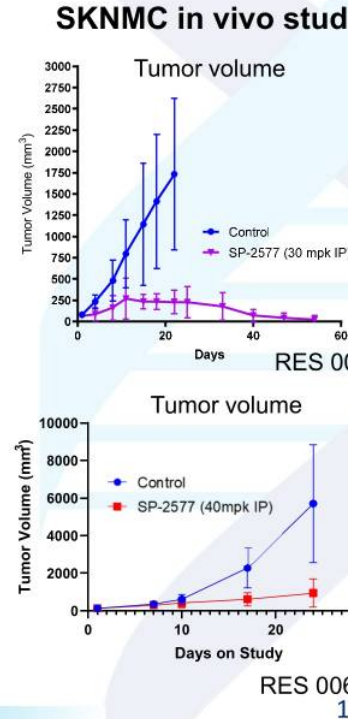
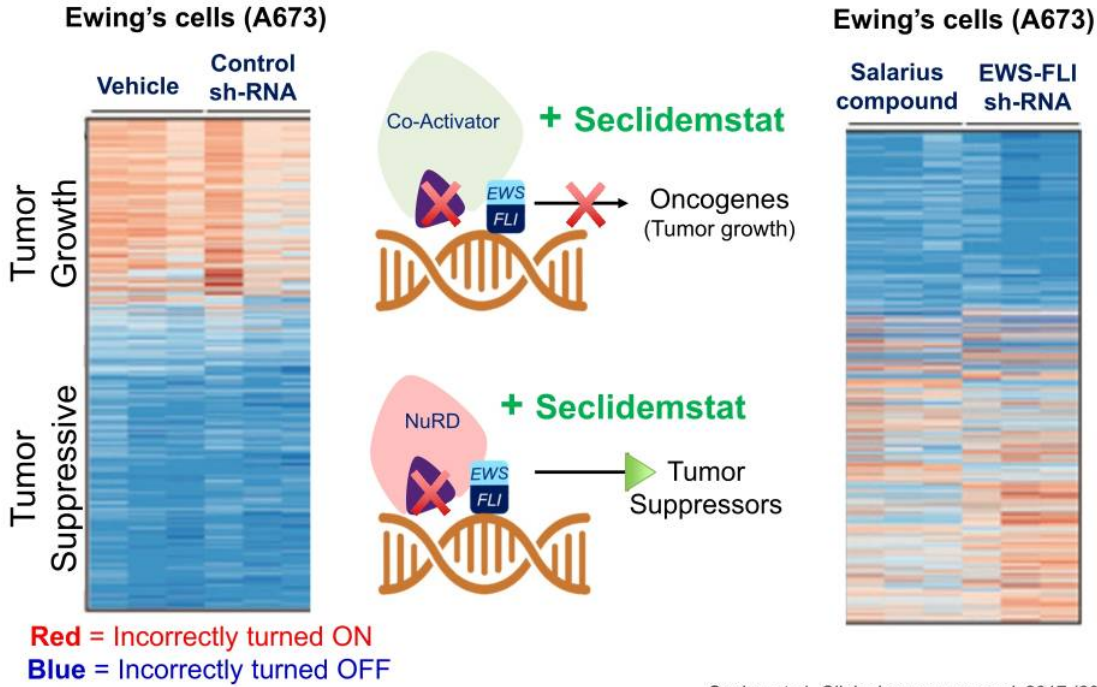


Red = Incorrectly turned on
Blue = Incorrectly turned off

Sankar et al. *Clinical cancer research*



Seclidemstat Reverses Ewing Sarcoma Gene Expression



Sankar et al. *Clinical cancer research* 2017 (2014)



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Ewing Sarcoma Phase 1 Progressing through Dose Escalation



Currently Enrolling
at 6 Clinical Sites

Adding 2 More

Open-label dose escalation / dose expansion study design

- **Dose escalation:** ~16 patients → On track to establish MTD by 1H2020
- **Dose expansion:** ~20 patients at MTD → Potential for reporting early cohort data in mid-2020

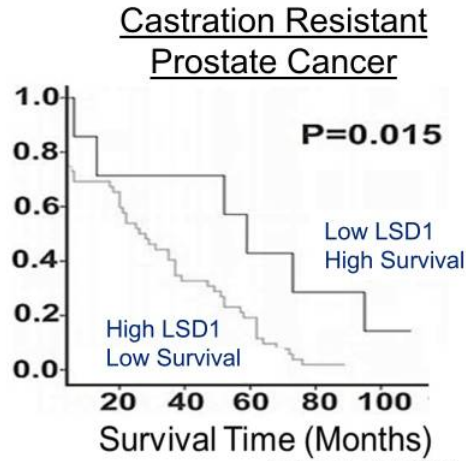
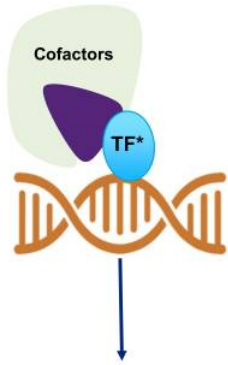


**Market Expansion:
Seclidemstat in Advanced
Solid Tumors**

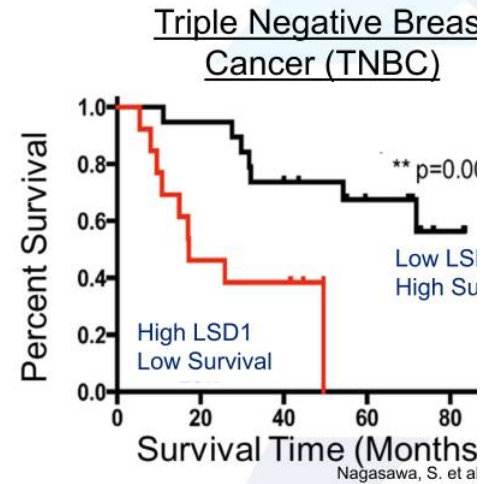


LSD1 Expression Levels are Correlated with Poor Patient Prognosis Across Several Cancer Types

LSD1 associates with different cofactors to drive disease progression across various indications



Kashyap, V., et al. (2013).



Nagasawa, S. et al.

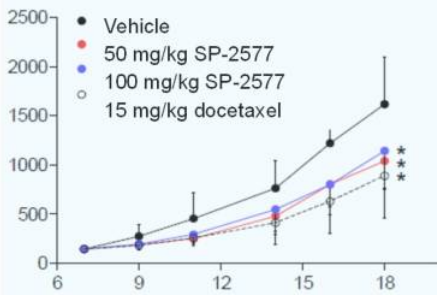
*transcription factors vary based on cancer type



Internal and External Data Demonstrate Single Agent Activity in Hard to Treat Cancers

Prostate Cancer

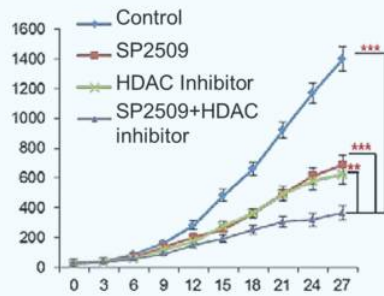
Seclidemstat slows tumor growth in difficult to treat 22RV1 androgen variant animal model



RES 007 Salarius

Triple Negative Breast Cancer

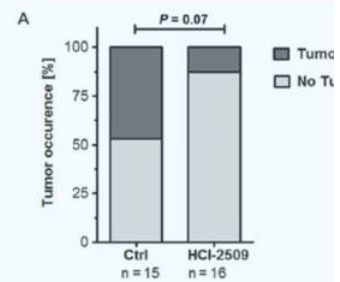
Seclidemstat analog showed ~50% single agent activity, and synergy with an HDAC inhibitor



Cao, Chunyu, et al. *International journal of cancer* (2018)

Non-Small Cell Lung Cancer

Seclidemstat analog decreased tumor occurrence in tumors driven by EGFR KRAS mutations



Macheleidt, Iris F., et al. *Molecular Oncology* (2018)



AST Clinical Trial Overview



Open-label dose escalation / dose expansion study design

- Enrolling advanced malignancies and enriching for indications Seclidemstat has shown efficacy
 - Prostate, breast, patients with specific genetic backgrounds + others
- Potential for early signs of therapeutic activity with established biomarker
- Early cohort readouts in mid-2020



Future Opportunities




Therapeutic Options for Seclidemstat

1 Monotherapy
Currently in clinical proof-of-concept. Preclinically, Seclidemstat has anti-tumor activity across range of cancer types

2 Synergy with chemotherapy
Preclinically, LSD1i shows ability to re-sensitize cells to standard of care agents

3 Synergy with targeted agents
Seclidemstat and its analog shows synergy with other agents such as PARP, EGFR, HDAC, DNMT1 inhibitors

4 In combination with checkpoint inhibitors
Seclidemstat may increase tumor immunogenicity influencing T cell infiltration, antigen presentation



Salarius' ongoing clinical preclinical work will further clarify the best options for different patients.



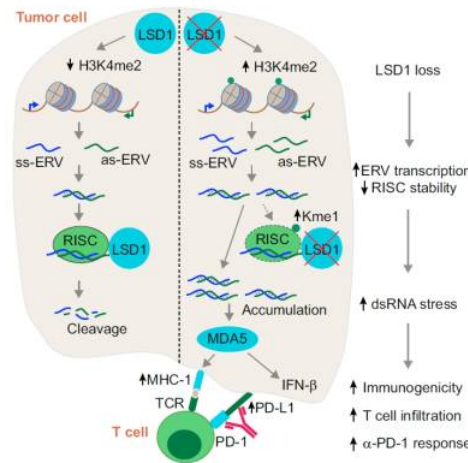
LSD1 Ablation Improves Immunotherapy Efficacy

Cell

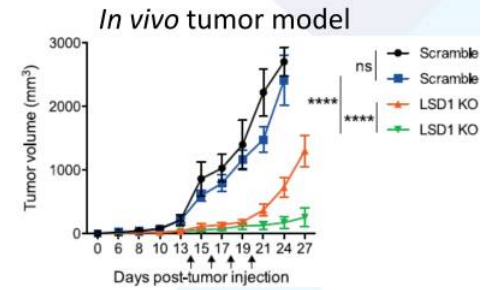
Article

LSD1 Ablation Stimulates Anti-tumor Immunity and Enables Checkpoint Blockade

- LSD1 ablation leads to activation of the IFN pathway and **increases a tumor's immunogenicity**
- Provides a potential therapeutic options for immune-refractory patients



"Cold" tumors turn "hot"



LSD1 KO +PD-1 treatment leads to significant tumor volume reduction



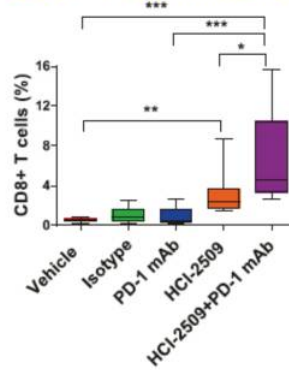
Secclidemstat Analog Shows *in vivo* Synergy with Anti-PD-1

Oncogene

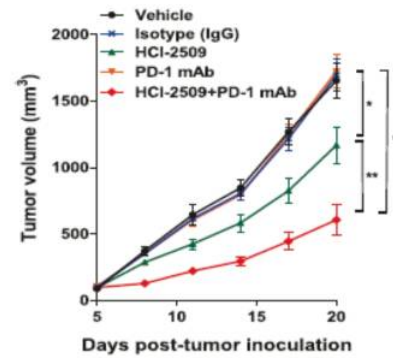
Inhibition of histone lysine-specific demethylase 1 elicits breast tumor immunity and enhances antitumor efficacy of immune checkpoint blockade

- Fewer than 20% of TNBC patients respond to checkpoint inhibitors
- *In vivo* studies showed significant increase in CD8+ T cells and tumor growth suppression for single agent therapy
- Saliarius compound sensitizes refractory tumor to checkpoint inhibition

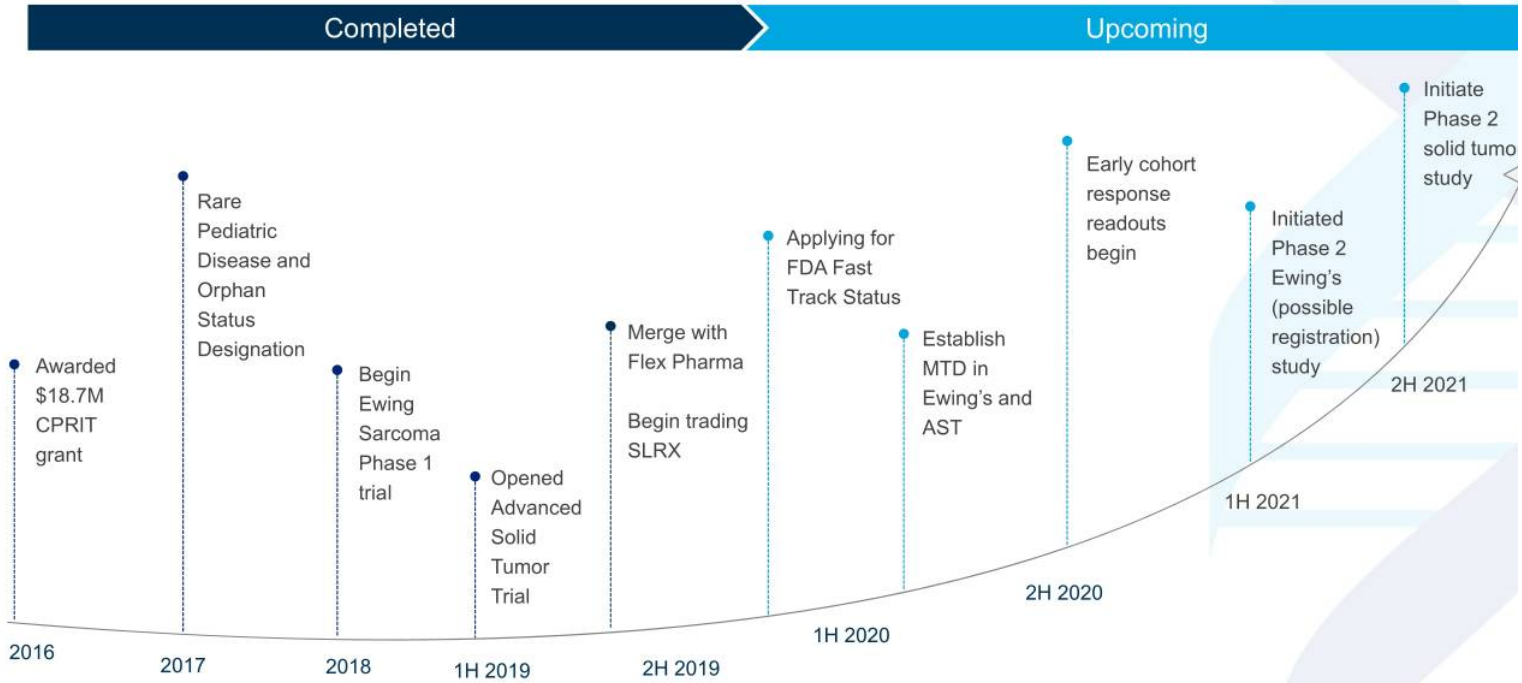
CD8+ T cell infiltration



EMT6



Salarius' Development and Future Milestones



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Investor Highlights: Salariaus Pharmaceuticals is an Epigenetic Focused Clinical-stage Oncology Biotech Company

- 1 Salariaus has a differentiated LSD1 inhibitor with expected human data in 2020**
 - Multi-company interest and clinical data validates LSD1 as a therapeutic target
- 2 Development strategy focused on Speed to Market and Market Expansion**
 - Speed to Market: Ewing sarcoma trial → Rare Pediatric Disease and Orphan Status Designation
 - Market Expansion: Advanced Solid Tumor trial → Hormonal cancers, sarcomas (\$1B+ markets)
- 3 Seasoned management team leading Salariaus**
 - Experienced in product, clinical and early stage development
- 4 Lead clinical program funded by extensive non-dilutive capital**
 - \$18.7M CPRIT award and support from the National Pediatric Cancer Foundation
- 5 Opportune time to capitalize on growth potential**
 - Potential to expand into other indications of high value (including immunotherapy)
 - Relatively short timeline to pivotal inflection points





Thank you!



