Initiation Report

SALARIUS PHARMACEUTICALS, INC.

Company Sponsored Research
Initiation of Coverage
12/16/2019

Salarius Pharmaceuticals, Inc. (NASDAQ: SLRX)

Biotechnology

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Clinical Stage Epigenetics Company Developing Targeted Therapies to Treat Pediatric and Adult Cancers

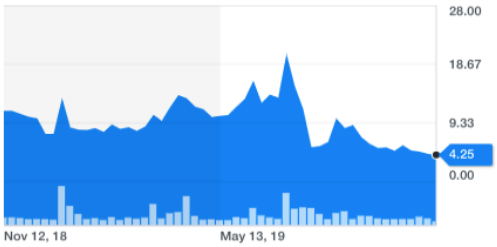
Investment Highlights:

- **Salarius' Seclidemstat is a clinical stage differentiated LSD1 inhibitor with human data expected in 2020.** Seclidemstat is a small molecule oral therapeutic targeting LSD1, an epigenetic "eraser", with a scientific basis to treat multiple cancer types and which could potentially be used in combination with other approved agents like checkpoint inhibitors, a large additional market. Salarius has two ongoing clinical trials, the first in Ewing sarcoma, a rare pediatric cancer, and the second in advanced solid tumors like breast/ovarian/prostate cancers, which could lead to a potentially expanded market for the drug. Seclidemstat is differentiated in the LSD1 market by its reversible mechanism and binding location facilitating the inhibition of enzymatic and scaffolding properties, which can potentially impact the therapeutic activity of cancer treatments. The epigenetics market is in high growth, with the market projected to reach $1.6 billion by 2022[1] with few pure play investment opportunities. *We view Salarius a unique high-risk high reward early stage epigenetics investment opportunity.*
- **Active Phase 1 acquisition and R&D collaboration market as Big Pharma looks to expand pipelines.** Based on our analysis of phase 1 Pharma acquisitions and R&D collaborations in the previous five years, if Salarius has positive phase 1 data there could be a significant correction in the share's valuation upwards as it could allow them to secure a collaboration deal or potentially be acquired. While pharma deals are impossible to predict, there is a potential for shareholder value creation in 2020 as early data is released from their ongoing Phase I Ewing sarcoma trial. If the data proves meaningful and absent an acquisition, positive data could allow the company to pursue a secondary offering funding a larger phase two trial, increasing scientific data and shareholder value.
- **Possible Pediatric Priority Review Voucher provides investors a free call option.** Ewing sarcoma is a rare pediatric disease affecting children and adolescents with no treatment beyond standard chemotherapy, disfiguring surgery or radiation, as such the company is eligible to receive a Pediatric Priority Review Voucher from the FDA, which can be sold, historically for over $100 million transaction values.
- **Company historically has sought out non-dilutive financing.** Salarius was awarded an $18.7 million grant from the Cancer Prevention & Research Institute of Texas (CPRIT) with the company receiving $9.3 million thus far as of recent quarter. Salarius also receives support from the National Pediatric Cancer Foundation.
- **Valuation relatively modest at $17 million.** Despite the unique value Salarius offers with its novel Seclidemstat technology and the limited number of public epigenetic companies, it currently trades at a lower technology value than other early stage oncology companies and what is indicated by a discounted cash flow model. Our blended discounted cash flow and technology value analysis models indicates a fair value of $9.00 per share, with the near-term catalysts being Ewing sarcoma safety and efficacy data and expansion to other indications.

Company Description

Salarius Pharmaceuticals, Inc. is an epigenetic focused clinical-stage oncology company developing therapies for the treatment of various cancers such as Ewing sarcoma and advanced solid tumors. The company is headquartered in Houston, Texas.

Price-Volume History



Source: Yahoo Finance

Key Statistics

Closing Price (as of 12/13/2019)	$4.19
52-Week Range	$2.91-$14.82
Average Daily Volume ('000s)	24.93
Shares Outstanding ('000s)	4,069
Market Capitalization (mn)	17.05
Number of Analysts Covering	1
Enterprise Value/Revenue	N/A

Revenue ($ in millions)

Dec. FY	2018A	2019E	2020E
FY	1.95A	3.32E	6.00E

EPS ($)

Dec. FY	2018A	2019E	2020E
FY	N/A	(1.98)E	(0.88)E

1-"Epigenetics Market." Market Research Firm, https://www.marketsandmarkets.com/PressReleases/epigenetics-technologies.asp.

Investment Summary

Salarius Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on developing effective epigenetic-based cancer treatments for indications with high unmet medical need. Epigenetics refers to the regulatory system that affects gene expression. In some cancers, epigenetic regulators often become dysregulated and incorrectly turn genes on or off leading to cancer progression. Drugs that can safely modify the activity of these epigenetic regulators may correct the gene changes that are driving the cancer progression. The company is running two Phase I clinical trials with its lead candidate, Seclidemstat, a small molecule oral therapeutic that targets LSD1, a key regulator of gene expression involved in promoting development of several cancer types which could potentially be used in combination with other approved agents like checkpoint inhibitors, a large market opportunity. As such, Salarius has been awarded an $18.7 million CPRIT grant to fund development of its LSD1 program. Salarius is first targeting a rare pediatric disease, Ewing sarcoma, as part of its speed to market strategy. Due to the high unmet need for novel Ewing sarcoma treatment options, Salarius has received and continues to receive funding from the National Pediatric Cancer Foundation and also has been deemed eligible for a Pediatric Priority Review Voucher, which can be potentially sold to another pharmaceutical company for over $100 million if it's in line with historical rates, or be used by Salarius to receive expedited review on another drug program.[1] We view Salarius as providing investors a unique, high risk high reward small capitalization epigenetics investment opportunity, with its differentiated potential treatments. Seclidemstat is a novel, reversible, and non-competitive LSD1 inhibitor to treat several types of cancer. Salarius' strategy consists of a speed to market and market expansion, an approach that has been successfully implemented by other biotech companies (e.g. Epizyme). Speed to market is achieved by treating Ewing sarcoma, a rare bone and soft tissue cancer, which affects children and adolescents with no treatment options beyond standard chemotherapy, as well as disfiguring surgery or radiation. There are no second-line treatment options for patients who have failed these first line therapies and 70% of patients with relapsed/metastatic disease will succumb to the disease.[2] Market expansion is achieved by studying Seclidemstat's potential as a more effective and less toxic treatment option in large market indications including prostate, breast, and ovarian cancers. Seclidemstat is well positioned and differentiated by its reversible mechanism and comprehensive inhibition of enzymatic and scaffolding properties, which can potentially enhance the therapeutic activity and improve potential efficacy in a broad range of cancer types. The company is conducting two open-label and dose-ranging Phase I trials of Seclidemstat in Ewing sarcoma and Advanced Solid Tumors with expected early human readouts in 2H 2020. Based on our analysis of phase 1 Pharma acquisitions and R&D collaborations over the past five years, the company's value could reset via upfront and/or royalty/milestone payments if the Ewing Sarcoma trial is successful.[3] Salarius is additionally one of the few pure play public investment opportunities within the rapidly growing epigenetics sector, the other public ones being Epizyme (EPZM), Oryzon Genomics (ORY.MC) and Constellation Pharmaceuticals, Inc. (CNST) with other epigenetic drugs being developed within larger diversified biotechnology companies (e.g. Celgene, GSK). We thus view *Salarius as presenting a relatively unique high-risk high reward investment opportunity within the small capitalization epigenetics sector.*

Salarius is developing Seclidemstat, a differentiated LSD1 inhibitor addressing areas of high unmet need

Possible Pediatric Priority Review Voucher provides investors a free call option

Salarius could see a significant valuation reset if its Phase 1 Ewing sarcoma trail is successful in late 2020

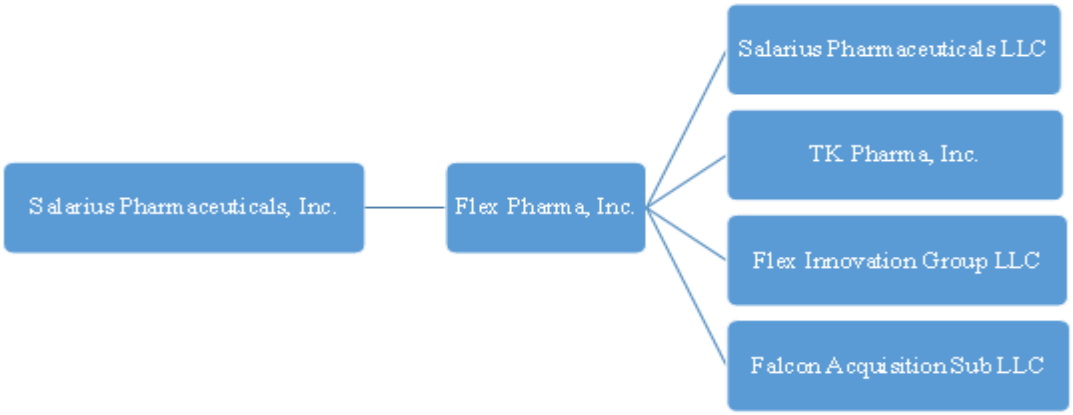
[1] Based on average selling price, see Appendix A
[2] Pishas, Kathleen I and Stephen L Lessnick. "Recent advances in targeted therapy for Ewing sarcoma" F1000Research vol. 5 F1000 Faculty Rev-2077. 25 Aug. 2016
[3] Based on average deal value, see Appendix B

Company Overview

Salarius Pharmaceuticals, Inc. (SLRX) is a clinical-stage oncology company, based in Houston, Texas. The company develops targeted therapies to treat cancer using technology targeting the epigenetic causes of cancer. Epigenetics is the controlling system that affects gene expression without involving changes to underlying DNA. In some cancers, epigenetic regulators incorrectly alter gene expression, which has been linked to cancer progression. Salarius develops drugs that can safely modify the activity of these epigenetic regulators, attempting to limit the progression by correcting the gene changes leading to disease. The company's lead epigenetic enzyme technology was licensed from the University of Utah Research Foundation in 2011. The company was established in 2011 in Salt Lake City, USA. Upon receiving the CPRIT grant, the company relocated to Houston, Texas, in 2016. In July 2019, the company completed its merger with Flex Pharma and began trading on the NASDAQ.

Salarius is developing therapies to treat cancers with a high unmet need. The company's lead candidate is Seclidemstat novel, reversible, and non-competitive LSD1 inhibitor

Exhibit 1: Corporate Structure of Salarius Pharmaceuticals

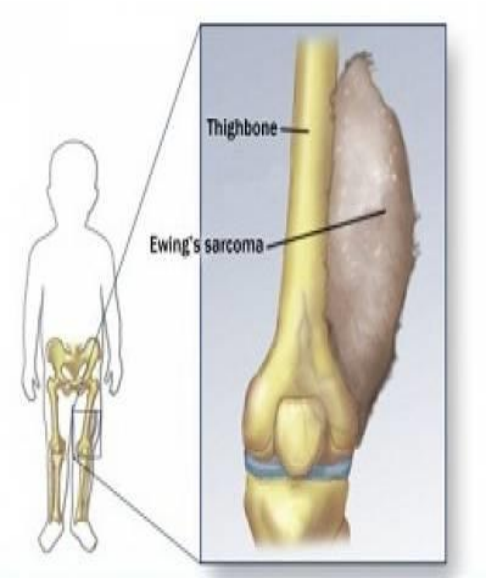


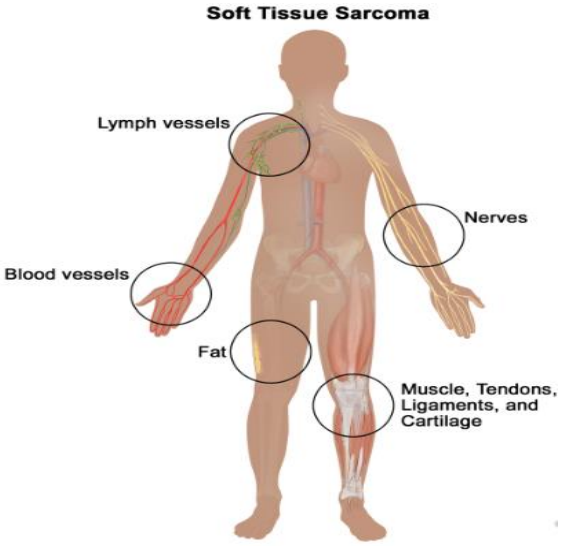
Source: Salarius Company Presentation, October 2019

Salarius is currently focused on developing its lead compound, Seclidemstat (SP-2577), as a targeted treatment for various cancer types. The company's speed to market/market expansion strategy is similar to the one taken by Epizyme ($1.5 billion market cap) in its development of tazemetostat, which currently has one submitted New Drug Application (NDA). Seclidemstat's initial indication of interest is Ewing sarcoma, where it is in Phase 1 of clinical development. Ewing sarcoma is a rare and devastating bone and soft-tissue cancer that mostly afflicts children and young adults, with a median age of diagnosis of 15 years. There are no targeted therapies currently available to treat/limit this deadly cancer.

Salarius strategy is similar to Epizyme's strategy in developing its lead epigenetic compound, tazemetostat

Exhibit 2: Ewing sarcoma and Soft tissue sarcoma



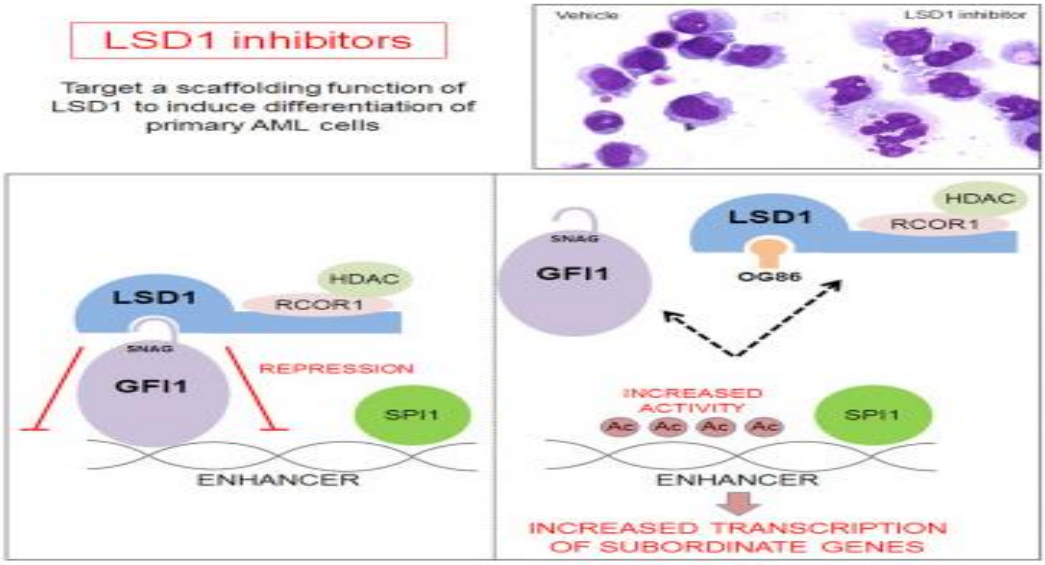


Source: Diamond Equity Research, OHSU Knight Cancer Institute

Salarius' lead compound, Seclidemstat is a reversible inhibitor of LSD1

Unlike many other compounds under development, Seclidemstat is a reversible inhibitor of lysine-specific demethylase 1 (commonly known in the pharmaceutical world as LSD1). LSD1 is an epigenetic regulatory enzyme, which is known to promote disease progression and its expression is often correlated with poor patient prognosis. LSD1 carries out its disease progression through both its enzymatic and scaffolding functions. Its enzymatic activity consists of eliminating mono- and di-methyl marks on histones (the core protein of chromatin) to alter gene expression. LSD1 can also act as a scaffolding protein (building block) of larger protein complexes, independently of its enzymatic activity, to alter gene expression. Given its bi-functional role in promoting disease progression, LSD1 has been a target of interest for drug development. Recent work has increasingly validated LSD1 as a clinically relevant therapeutic target of interest. Several companies have shown promising clinical data and raised significant capital (e.g. Imago, Oryzon). This bodes well for Salarius, especially considering its differentiation from the aforementioned direct competitors at inhibiting LSD1's scaffolding properties.

Exhibit 3: Lysine Specific Demethylase 1: The epigenetic regulatory enzyme



Source: Cell.com, study on LSD1

LSD1 is at the center of interest given its role in cancer progression via its demethylation independent activity

Interestingly, outside of its role in promoting disease progression, LSD1 is required to maintain stem cells and guide differentiation of certain healthy cells, such as blood cells. For this reason, it is important to carefully modulate LSD1's activity to a level that can prevent cancer progression (where it acts irrationally to alter gene expression), but not detrimentally alter its role in healthy cells and cause hematological toxicity. Consequently, Seclidemstat's reversibility might offer it an advantage over some of its competitors that are irreversible inhibitors of LSD1.

LSD1 is associated with over 60 gene regulatory proteins – EWS-FLI1 is one of them

Salarius' first target indication is Ewing sarcoma. Ewing sarcoma is driven by a chromosomal translocation that causes a fusion oncoprotein. EWS-FLI1 is the most commonly expressed fusion oncoprotein, present in approximately 85% of Ewing sarcoma cases. The LSD1 enzyme associated with EWS-FLI1 and promotes tumorigenesis. Seclidemstat could be applied here, as this molecule could help stop EWS-FLI1 from interacting with LSD1, thereby limiting cancer-promoting activity. Seclidemstat could also reverse abnormal gene expression, halting Ewing sarcoma cell production (or even killing cancerous cells).

Since LSD1 interacts with over 60 regulatory proteins outside of EWS-FLI1, LSD1 also plays a role in disease progression of several other cancer types. Hence, Salarius is conducting a 2nd clinical trial in Advanced Solid Tumors. This trial supports Salarius' market expansion strategy, as showing efficacy in an indication such as prostate, breast or ovarian would capture a large market and greatly increase Seclidemstat's value.

Another, newer area of interest for LSD1 inhibition is the immunotherapy field. Several recent studies suggest that LSD1 plays a role in suppressing the immune

system (immunosuppression). This has led to increased interest in exploring LSD1 inhibition for use in combination with checkpoint inhibitors, which would add tremendous value to Seclidemstat. According to the BCC Research "Checkpoint Inhibitors: Global Markets" report the global checkpoint inhibitor market is projected to reach $29.3 billion by 2023 growing from approximately $14.9 billion in 2018, at a compound growth rate of 14.4% over the period. However, an opportunity exists for patients who remain refractory to checkpoint inhibitors (43% of patients in the U.S. with cancer are ineligible for checkpoint inhibitors)[4], such as exploring ways to increase sensitization which is an active area of study and a potential area where Seclidemstat could be used in combination with checkpoint inhibitors.

Salarius is targeting Ewing sarcoma with a potentially more effective and less toxic treatment option

As per Salarius, Seclidemstat's increased efficacy compared to some of its competitors is due to two factors: (1) its ability to inhibit demethylation (i.e., LSD1's enzymatic activity) and (2) its ability to reduce the scaffolding properties of LSD1. Seclidemstat showed itself to be potentially safe (no hematological toxicity) during the clinical-enabling stage, derived mainly from its reversible binding characteristics, in contrast to molecules developed by most of the competitors that are irreversible inhibitors of LSD1 and have shown hematological toxicity.

Salarius is in the process of actively studying LSD1 inhibition. For this research, Salarius received an award of $18.7 million from CPRIT. Preclinical studies of the compound have shown a significant reduction in cancerous cells (in certain Ewing sarcoma animal models, whose survival rates have increased significantly). Seclidemstat has also shown promising preclinical activity in other advanced cancer types (e.g. breast, prostate). Seclidemstat is being currently studied in two dose escalation / expansion clinical trials.

- Salarius is currently conducting a Phase 1/2 dose-escalation study in adolescents and young adults with relapsed or refractory Ewing sarcoma.
    - Salarius intends to enroll up to 50 relapsed or refractory Ewing sarcoma patients for the Phase 1 trial.
    - The study is being conducted at eight centers in the U.S. (Exhibit 6).
    - Salarius intends to assess the safety, efficacy, and tolerability of the oral Seclidemstat dose and establish the maximum-tolerated dose (MTD).
    - The company is currently in dose escalation in cohort 4 in the Ewing Sarcoma study.
- To study the Seclidemstat compound further, Salarius initiated a second company-sponsored Phase 1 trial in Advanced Solid Tumor (AST) during the second quarter of 2019.

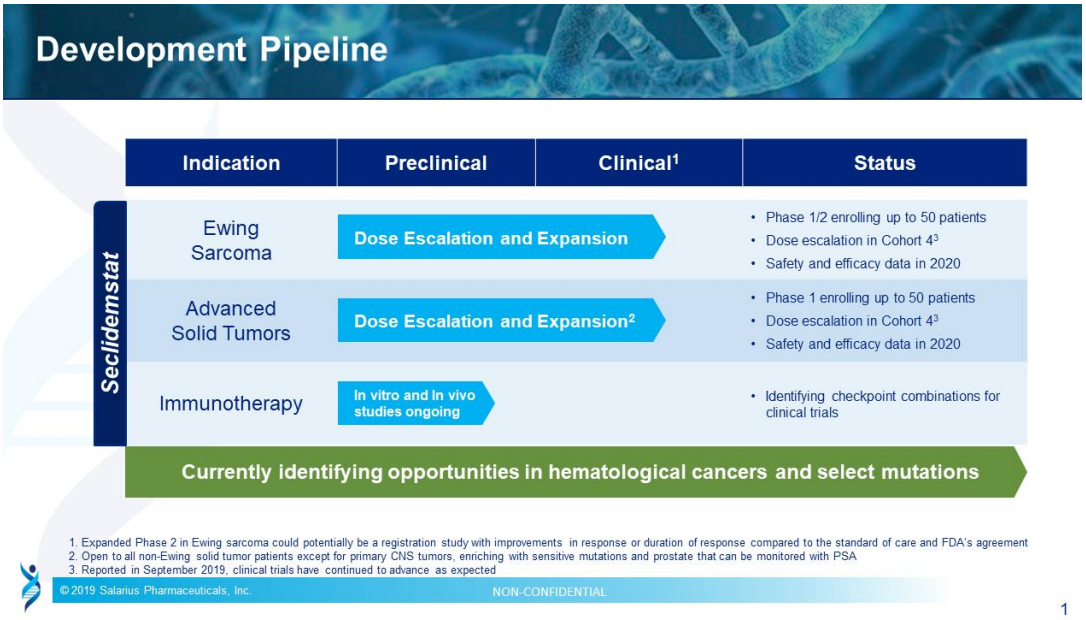
Salarius has already initiated Phase 1 clinical trials, with preclinical studies showing positive results

[4] Haslam, Alyson, and Vinay Prasad. "Estimation of the Percentage of US Patients With Cancer Who Are Eligible for and Respond to Checkpoint Inhibitor Immunotherapy Drugs." JAMA Network Open, American Medical Association, 3 May 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6503493/.

- The trial will study the effect of single-agent dose escalation (excluding Ewing sarcoma and/or central nervous system tumors).
- The company is currently in dose level 4 in the AST study as of September 24, 2019.

Exhibit 5: Salarius' drug development pipeline and stages

Salarius is also broadening its pipeline to treat other cancers including Advanced Solid Tumors



Source: Salarius Corporate Presentation

1. Advanced Solid Tumor Study is open to all non-Ewing solid tumor patients except for primary CNS tumors
*Expanded Phase 2 in Ewing sarcoma could potentially be a registration study following discussions with the FDA regarding improvements in response, duration of response compared to SOC

Salarius initiated the clinical trials in 3Q 2018. Several patients had been treated with various dose levels (dose level 4 being the highest) as of September 2019.

Human data readouts are expected in late 2020

Table 1: Dose escalation levels - Seclidemstat

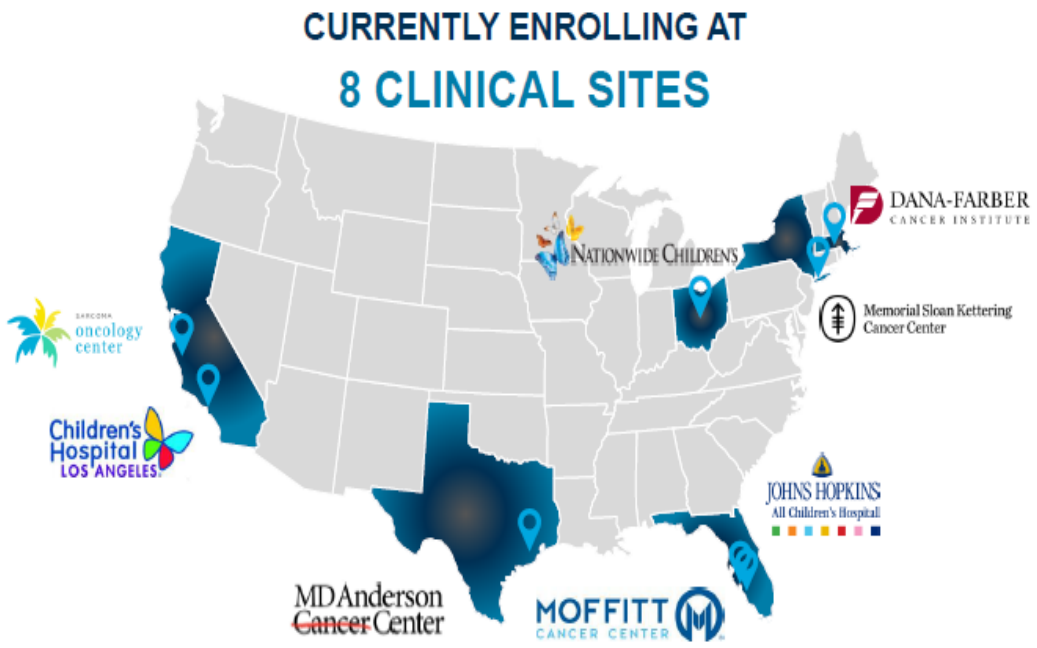
Dose Level	Twice Daily Dose (mgs)	Percent increase from preceding dose level	Total Daily Dose (mgs)
1	75	0	150
2	150	100%	300
3	300	100%	600
4	600	100%	1200
5	900	50%	1800
6	1200	33%	2400
7	1500	25%	3000

Source: Diamond Equity Research, Salarius Pharmaceutical SEC filing, October 2019

The safety and efficacy data is scheduled to be released in the first half of 2020. Following this, the company will move into the dose-expansion part of the study,

where it will gather additional safety, tolerability, and pharmacokinetic data and evaluate Seclidemstat's anti-tumor activity.

Exhibit 6: Salarius' clinical trial sites for Ewing sarcoma patients



Source: Company presentation, October 2019

Salarius' strategic collaborations and license agreements

Salarius has collaborated with many institutions for existing and expanded cancer studies

Salarius works with renowned doctors and scientists and top medical institutions. The company entered into an exclusive licensing agreement with the University of Utah Research Foundation in August 2011 to license exclusively its lead compound Seclidemstat (SP-2577) and related compounds. In return, the University of Utah received a 2% membership interest in Salarius. This licensing arrangement is effective until 2037. In November 2016, HLB life Science, a South Korea-based pharmaceutical company, entered into a sublicensing arrangement with Salarius for SP-2577 for the right to develop, produce, manufacture, use and sell the drug in South Korea. In June 2016, Salarius received a three-year $18.7 million new-company product development award from the Cancer Prevention and Research Institute of Texas (CPRIT). The contract lapsed on May 31, 2019, but the CPRIT extended it by six months (to November 30, 2019) with additional extensions available. In August 2019, the Ivy Brain Tumor Center at the Barrow Neurological Institute entered into

a research agreement with Salarius for further study of SP-2577 to test for the treatment of glioblastoma.

Corporate timeline

- October 28, 2019 – Aspire Capital Fund, LLC, a Chicago-based institutional investor, entered into a $10.9 million common stock purchase agreement with Salarius, including a $1.0 million initial common stock purchase
- August 26, 2019 – Salarius entered into a research agreement with the Ivy Brain Tumor Center at the Barrow Neurological Institute
- July 22, 2019 – Salarius began trading on the Nasdaq Capital Market under ticker symbol SLRX
- July 19, 2019 – Salarius concluded its merger with Flex Pharma, Inc.
- January 3, 2019 – Salarius and Flex Pharma entered into a merger agreement
- November 25, 2016 – Salarius entered into an exclusive pharmaceutical sublicensing agreement with HLB Life Science
- June 1, 2016 – Salarius received a product development award from CPRIT
- August 3, 2011 – Salarius entered into an exclusive licensing agreement with the University of Utah Research Foundation for SP-2577
- May 2011 – Salarius is incorporated in Salt Lake City

Salarius Key Investors

Salarius' R&D is supported by investors who support the company's objective of providing preventive treatment to patients afflicted with devastating bone and soft-tissue cancers. This is evident from the recent stock purchase arrangement entered into by Aspire Capital Fund, LLC (Aspire), which is a Chicago-based institutional investor. Aspire bought $1.0 million worth of common stock in October 2019, with a commitment to buy an additional $9.9 million of stock until 2022.

Salarius has received investor interest with its unique proposition , allowing continued R&D

Sunil Sharma is the largest shareholder in the company, with a 9.27% stake, and is one of the scientific advisors to Salarius. This holding is closely followed by Salarius Chairman Jonathan Northrup's 9.18% share. Institutional investors together hold a

5.5% stake; Douglass Winthrop Advisors LLC holds 2.1%, and Renaissance Technologies LLC holds 1.5%. The limited institutional ownership is not surprising given the stage of development and does not include Aspire recently opening a position.

Table 2: Salarius' top 10 shareholders

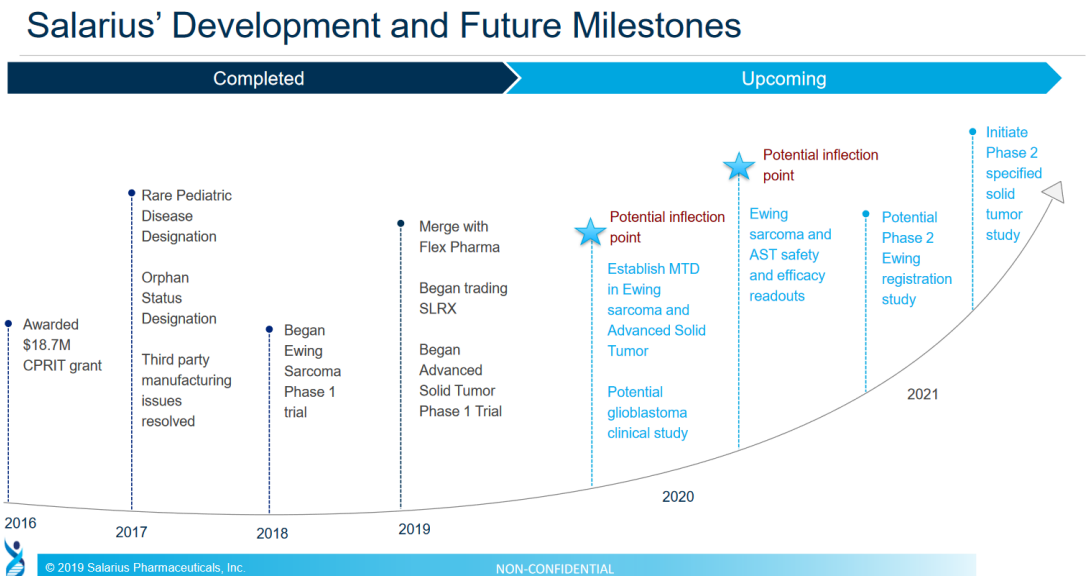
Key Shareholders	% OS
Sunil Sharma	9.27
Jonathan P Northrup	9.18
Green Park & Golf Ventures LLC	7.31
The Boston Foundation	2.35
David J Arthur	2.12
Douglass Winthrop Advisors LLC	2.10
Renaissance Technologies LLC	1.49
Wetherby Asset Management, Inc.	1.33
Geode Capital Management LLC	0.19
Ahrens Investment Partners LLC	0.15

Source: FactSet, as of September 30th, 2019

Potential Catalysts

- Positive results from phase 1 clinical trials in Ewing sarcoma and Advanced Solid Tumors in 2020
- Favorable early stage trial results of Seclidemstat's other programs
- New innovative product introductions from developing new cancer treatment for Glioblastoma
- Potential to expand into other indications of high value (e.g. immunotherapy)
- Achieving different types of synergies from the merger with Flex Pharma
- Larger financing at attractive terms, removing dilution risk
- More license agreements or partnerships to accelerate the development and commercialization of the product
- Successful acquisition at attractive terms by a larger strategic acquirer

Exhibit 8: Company Timeline



Source: Salarius Pharmaceuticals, 2019 Corporate Presentation

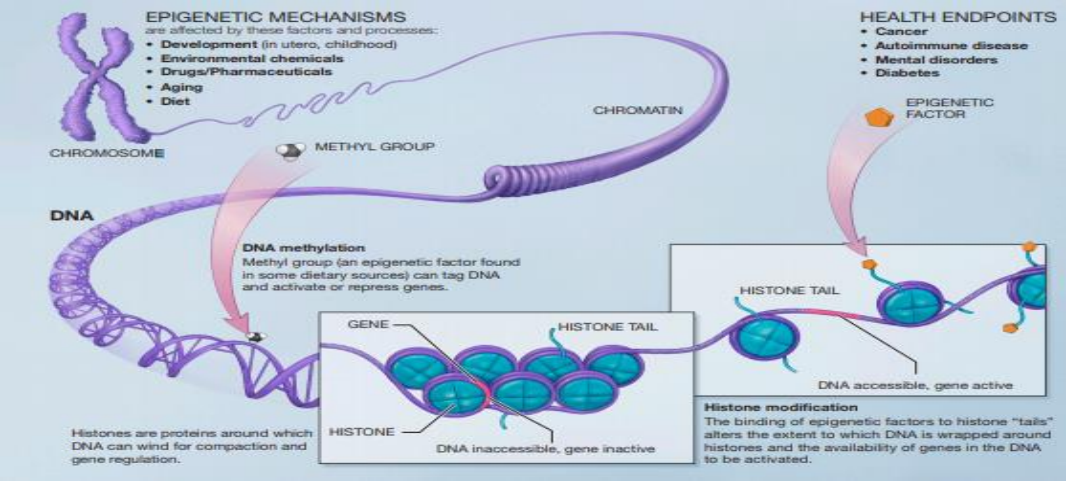
Cancer has traditionally been viewed as a disease driven primarily by the accumulation of genetic mutations. However, recent studies have now been expanded to include the disruption of epigenetic regulatory mechanisms that are also prevalent. The genetic path to cancer is relatively straightforward, i.e., the mutation of tumor suppressors and/or oncogenes leading to either loss or gain of function and abnormal expression, while the epigenetic way to cancer is determined by chromatin structure, including DNA methylation, histone variants and modifications, and nucleosome remodeling.

Two paths to cancer - Genetic path through mutation of tumor suppressors, and Epigenetic path via chromatin structure

Epigenetics is the study of modifications to DNA that change the way genes are expressed. They do not alter an individual's underlying genetic code. Epigenetic modifications affect an individual by turning genes on and/or off. According to Markets and Markets the global epigenetic drug market will likely reach $1.6 billion by 2022 from $854 million in 2017 and grow at a CAGR of 13.5%. We believe that with the advancement of epigenetic drugs through clinical development, Salarius is not receiving adequate investor attention. For example, it recently entered into $ 10.9 million stock purchase arrangement with Aspire Capital Fund, LLC, which is a Chicago-based institutional investor.

Global epigenetic drug market is expected to reach USD2.6bn by 2025 reflecting a 13.6% CAGR

Exhibit 8: Epigenetic mechanisms



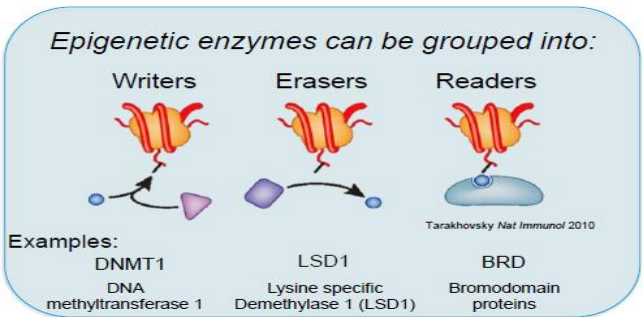
Source: National Institute of Health

Epigenetic mechanisms can be classified into three categories: DNA methylation, histone modification and genomic imprinting

Activation or repression of gene expression is driven by addition of methyl group (CH3) to DNA – most prominent being 5-methyl-cytosine (5-mC)

DNA methylation (DNMTs) add a methyl group (CH3) to DNA; this addition can lead to either the activation or the repression of gene expression. One of the most well-characterized DNA methylations is the addition of the methyl group at the 5-position of the cytosine nucleotide ring, which results in the formation of 5-methyl-cytosine (5-mC). Similarly, epigenetic factors bind to histone tails that change the extent to which DNA is wrapped around each histone. This alters the accessibility of genes. The most well-characterized histone modifications are the methylation and acetylation of H3 and H4. Genomic imprinting results in genes being expressed in a parent-of-origin-specific manner. Some genes are expressed from the maternally inherited allele, whereas others are expressed from the paternally congenital allele.

Exhibit 9: Epigenetic enzyme types

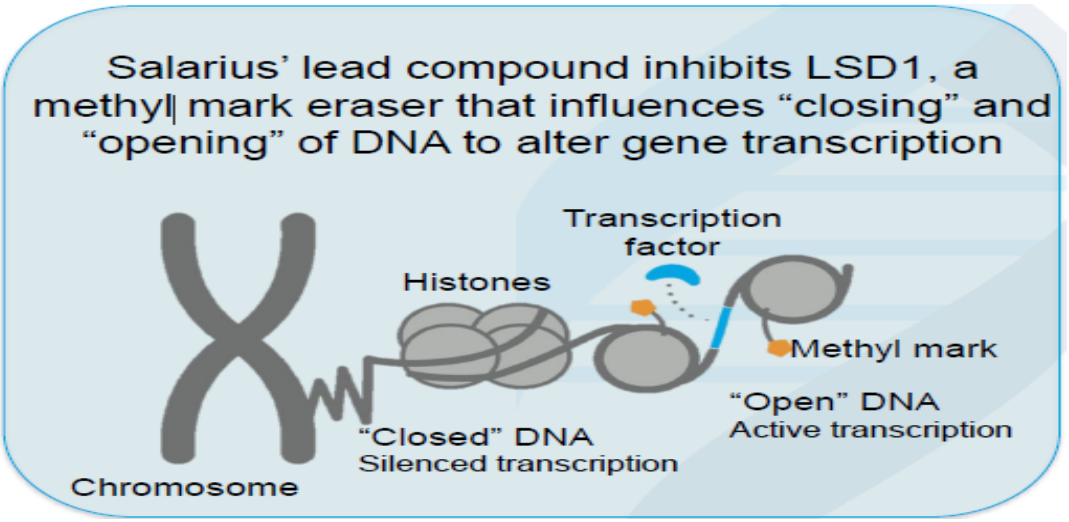


Source: Salarius Corporate Presentation, October 2019

Epigenetic enzymes modify chemical groups of chromatin (the structural component of chromosomes) to determine gene expression. Gene expression controls the type and number of proteins found in a cell. It depends on the location and number of chemical groups in chromatin, which determines whether any DNA is open or closed, i.e., whether gene expression can begin or not, respectively.

Gene expression are defined by modification of chemical groups of chromatin by epigenetic enzymes

Exhibit 10: Epigenetics – Gene expression through various chemical modification



Source: Salarius Corporate Presentation, October 2019

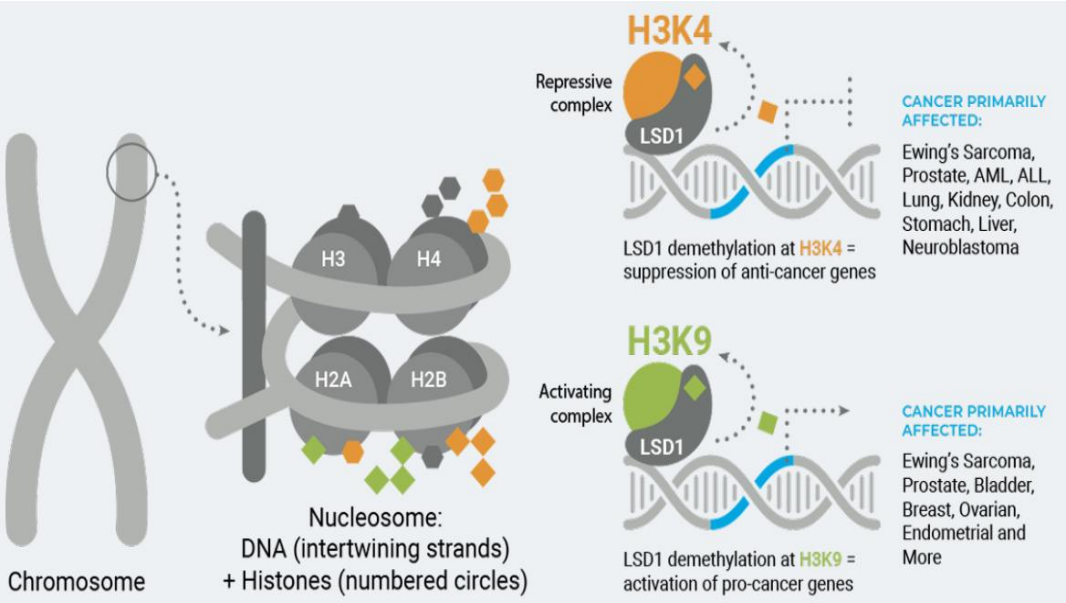
The first human disease to be linked to epigenetics was cancer, in 1983. Interest in cancer epigenetics has since continued to increase, with specific attention being given to the broadening understanding of different epigenetic mechanisms, including hypo and hypermethylation, loss of imprinting, and chromatin modification. A major reason for increasing interest of pharmaceutical companies and investors could be that novel epigenetic drugs are getting closer to potential FDA approval. For example, Epizyme, Inc., a U.S. based epigenetics company, filed an NDA for tazemetostat, for the treatment of metastatic or locally advanced epithelioid sarcoma not eligible for curative surgery.

Epigenetics has attracted attention of pharmaceutical companies and investors, as FDA approval is approaching for epigenetic drugs.

LSD1 and Ewing sarcoma: an attractive target for therapeutic study

LSD1 is being studied as an attractive target for cancer treatment. Recent clinical data supports LSD1 inhibition as a viable therapeutic strategy. LSD1 has two key functions: (1) the demethylation of histone H3 tails and other proteins and (2) acting as a scaffolding protein in epigenetic complexes. The cancer epigenome shows global hypomethylation; LSD1 demethylation at H3K4 and H3K9 is a contributing factor.

Exhibit 11: Epigenetic modulator, LSD1 in cancer



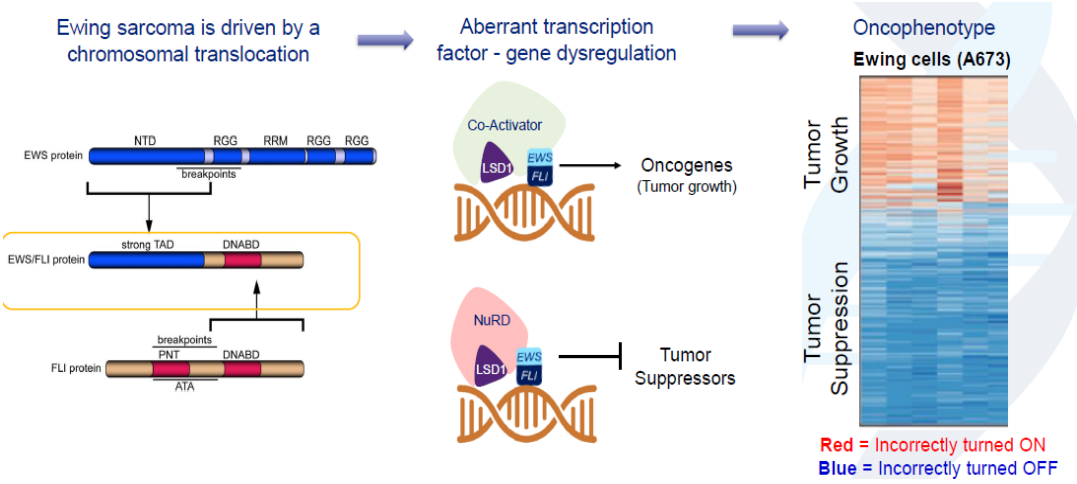
LSD1 inhibition seems feasible therapeutic approach for cancer treatment

Source: Salarius Corporate Presentation, October 2019

LSD1 inhibitors are being aggressively investigated in pediatric cancers and ASTs, and the results of early clinical trials should help inform the future use of LSD1 inhibitors in sarcoma. High LSD1 expression is observed in Ewing sarcoma patient samples, and mechanistic and preclinical data suggests that LSD1 inhibition globally disrupts the function of EWS-ETS proteins. Nearly 85% of cases express the EWS-FLI protein that functions as a transcription factor and drives oncogenesis. As the primary genomic lesion and a protein that is not expressed in normal cells, disrupting EWS-FLI function is an attractive therapeutic strategy for Ewing's sarcoma.

Ewing sarcoma patient samples reveal high LSD1 expression with preclinical data supporting LSD1 inhibition as disruptor of EWS-ETS proteins

Exhibit 12: Therapeutic opportunities in Ewing sarcoma



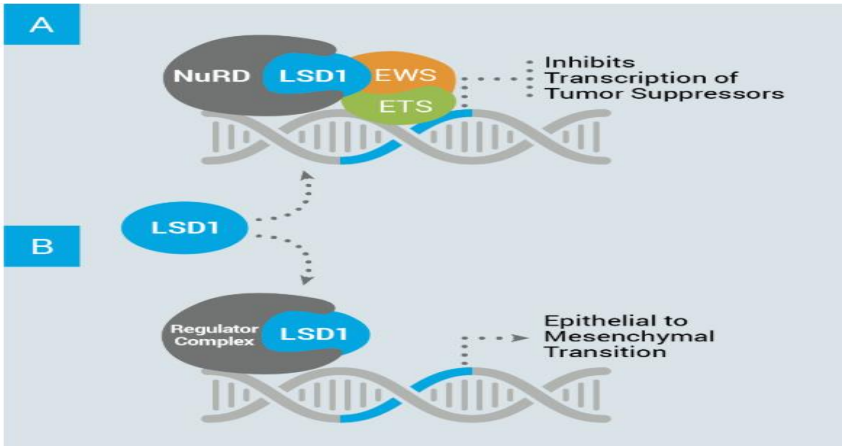
Source: Salarius Corporate Presentation, October 2019

Since LSD1's discovery as a histone demethylase about 12 years ago, the understanding of LSD1's structure and enzymatic mechanism has advanced relatively rapidly. Major steps taken in the development of enzymatic inhibitors has highlighted LSD1's apparent myriad cellular functions. We believe, Salarius has an advantage here. It is one of the early movers in the field and is in the clinical stage of developing a potentially effective and less toxic treatment option for Ewing sarcoma.

Salarius is undertaking clinical trials for potentially effective and less toxic option for cancer treatment

Salarius' lead compound Seclidemstat is a differentiated LSD1 inhibitor, with potential for increased efficacy and safety compared with other LSD1 inhibitors currently in clinical development. This compound has a promising safety profile that is potentially derived from its reversible binding. Salarius is researching and establishing the Seclidemstat safety profile in ongoing clinical studies.

Exhibit 13: LSD1's scaffolding properties can drive cancer growth in Ewing sarcoma



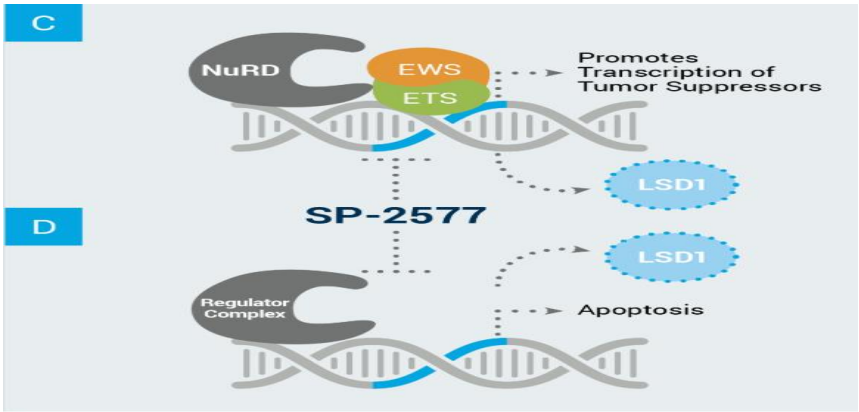
Source: Salarius Corporate Presentation, October 2019

(A) LSD1 acts in conjunction with other proteins, to prevent growth of tumor-suppressor genes. (B) LSD1 interacts with other proteins to disrupt the equilibrium of healthy cells, leading to expression of a stem cell-like phenotype.

Recent preclinical research suggests that modulation of LSD1's non-enzymatic functions, i.e., scaffolding functions, may be necessary for LSD1 inhibitors to have therapeutic activity in indications in which the irreversible catalytic inhibitors show limited or no efficacy. In contrast to the irreversible catalytic inhibitors, Seclidemstat interacts with a different region of LSD1 that causes it to inhibit not only LSD1's enzymatic activity, but also more of LSD1's scaffolding properties. Evidence suggests that Seclidemstat's differentiated mechanism of action may play a significant role in its therapeutic activity across a broader range of cancer types and, consequently, it's potential for broad clinical impact.

Seclidemstat's differentiated mechanism of action may play a significant role in its therapeutic activity across a broader range of cancer types

Exhibit 14: Seclidemstat inhibits LSD1's scaffolding properties



Source: Salarius Corporate Presentation, October 2019

(C) It allows for the transcription of tumor-suppressor genes, and/or (D) prevents transcription relating to self-renewal, leading to cell death.

Preclinical study suggests Seclidemstat reverses Ewing sarcoma gene expression

Ewing sarcoma is a high-grade sarcoma arising in bone or soft tissue and occurs most commonly in adolescents and young adults. The only treatments available so far are surgery and/or radiation. Patients are also treated with chemotherapy in an effort to eradicate the cancer. In North America, very young patients receive a combination of vincristine, doxorubicin, and cyclophosphamide alternating with ifosfamide and etoposide, along with planned chemotherapy (typically every two weeks). In Europe, they receive vincristine, ifosfamide, doxorubicin, and etoposide as the initial chemotherapy regimen. The usual localized therapy consists of up to 14 total cycles. However, around 25% of patients suffer relapses, despite the therapy. This rate is even higher (50-80%) for those with metastatic diseases, although the rate depends on the site of the metastases.

Current Ewing sarcoma treatment includes surgery and radiation, with ~25% of patients suffering relapses

Table 3: Conventional treatment of Ewing sarcoma with chemotherapy

Agent(s)	Number of published studies	Cumulative number of patients	Cumulative response rate	Main toxicities
Cyclophosphamide/ topotecan	3	79	32%	Myelosuppression
Gemcitabine/ docetaxel	3	24	29%	Myelosuppression Neuropathy
Ifosfamide	115	35	34%	Myelosuppression Neurotoxicity Renal insufficiency, Hematuria
Temozolomide/ irinotecan	713	166	47%	Diarrhea
Etoposide with carboplatin or cisplatin	136	107	29%	Myelosuppression
Oral etoposide	138	58	19%	Myelosuppression

Source: Management of recurrent Ewing sarcoma: challenges and approaches by David Van Mater, Duke University

This has encouraged several multinationals and specialized players to focus on further treatment options. Salarius' first trial is in a devastating bone and soft-tissue cancer – Ewing sarcoma. About 500 cases are diagnosed yearly in the U.S., afflicting children around a median age of 15. Currently available treatment leads to unbearable short- and long-term side effects. Additionally, patients with advanced solid tumors (such as prostate, breast, and ovarian cancers) who have found it difficult to respond to the current standard of treatments are seeking new potential treatments.

Salarius is focusing on treating Ewing sarcoma which affects children with median age of 15 years

Table 4: Selected studies of targeted therapies for Ewing sarcoma

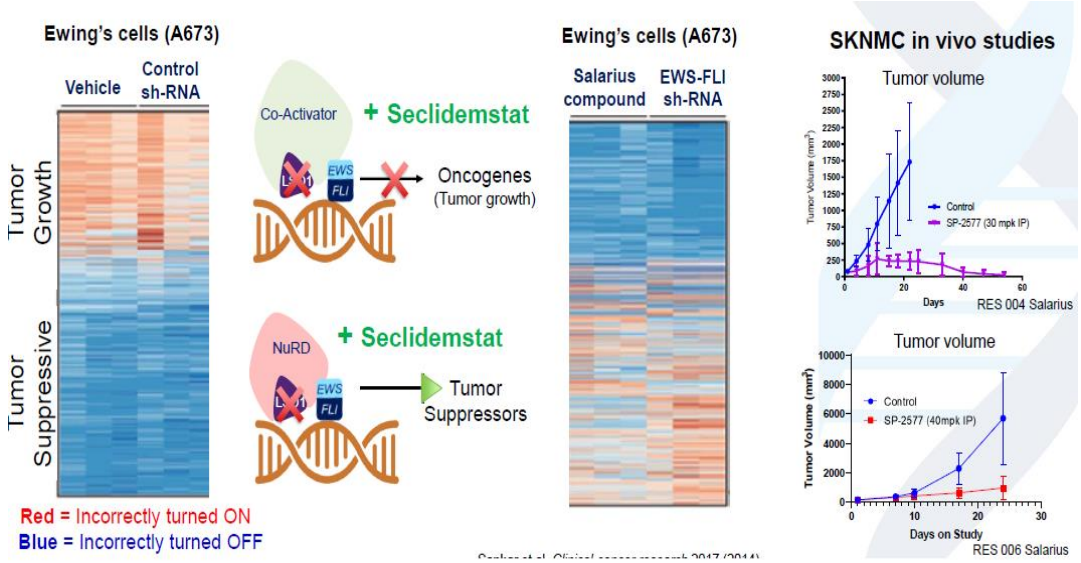
Agent	Target	Sponsor	Phase	Eligibility (age in years)	ClinicalTrials.gov identifier
Cabozantinib	*MET*	*Children's Oncology Group*	*1b*	*>12*	*NCT02867592*
TB-403	Placental growth factor	Beat Childhood Cancer	1/2	0.5-18	NCT02748135
INCB059872	LSD-1	Incyte	1b	>12	NCT03514407
SP-2577	**LSD-1**	**Salarius**	**1**	**>12**	**NCT03600649**
TK216	RNA helicase A	Oncternal	1	>10	NCT02657005
Linsitinib	IGF-1R	Eurosarc	2*	18-70	NCT02546544
Erlotinib/ temozolomide	Multiagent	Washington University	2	1-21	NCT02689336
Pazopanib	Multityrosine kinase inhibitor	Children's Oncology Group	2	1-18	NCT01956669
Pazopanib/ irinotecan/ temozolomide	Multiagent	UCSF	1	6-30	NCT03139331
Regorafenib	*VEGF*	*Sarcoma Alliance for Research through Collaboration*	*2*	*>10*	*NCT02048371*
Talazoparib/ temozolomide	Multiagent	NCI	1/2*	1-30	NCT02116777
Niraparib/ temozolomide ±irinotecan	Multiagent	Sarcoma Alliance for Research through Collaboration	1	>13	NCT02044120
Olaparib/ temozolomide± irinotecan	*Multiagent*	*MGH*	*1*	*>16*	*NCT01858168*
Trabectedin/ olaparib	*Multiagent*	*Italian Sarcoma Group*	*1b*	*>18*	*NCT02398058*
Cabozantinib	*MET*	*NCI*	*2**	*>12*	*NCT02243605*
Abemaciclib	CDK4/6	Emory	1	2-25	NCT02644460
Lurbinectedin	Transcription	PharmaMar	2*	>18	NCT02454972

Source: Management of recurrent Ewing sarcoma: challenges and approaches by David Van Mater, Duke University, ClinicalTrials.gov

*Completed study or not actively recruiting
Abbreviations: NCI: National Cancer Institute; MGH: Massachusetts General Hospital; UCSF: University of California, San Francisco
Chemotherapy treatments italicized

Preclinical data shows that Seclidemstat, and/or its analog compound, modulates EWS/ETS growth activity by selectively reducing the tumor-associated oncogenes and increasing tumor-suppressor function, leading to a reduction in Ewing sarcoma cells.

Exhibit 15: Targeting Ewing sarcoma with Seclidemstat



Ewing sarcoma cells are mitigated through modulation of EWS/ETS growth through Seclidemstat

Source: Salarius Corporate Presentation, October 2019

Notes:
Left: Seclidemstat analog inhibits LSD1 from associating with the oncoprotein EWS11; Right: Seclidemstat analog inhibits LSD1 from associating with the oncoprotein

Ewing sarcoma represents an attractive market opportunity for Seclidemstat because there are no standardized treatment options for patients who fail first-line standard of care therapy given it is a rare disease with a high unmet need, there is also possibility of accelerated approval Current options for these patients are limited and carry debilitating side effects. Despite the severity of the treatments, the long-term survival rate of these patients is dismal. Given the high unmet need that Ewing sarcoma presents, Seclidemstat was granted the Orphan Drug and Rare Pediatric Disease (RPD) designations by the U.S. FDA to facilitate and encourage its development process.

Seclidemstat was granted the Orphan Drug and Rare Pediatric Disease (RPD) designations by the U.S. FDA

Exhibit 16: Seclidemstat could receive a Priority Review Voucher of USD100m on Ewing sarcoma approval

Source: Diamond Equity Research, company presentation

Salarius could generate over $100 million PRV, once the company gets the FDA approval on Seclidemstat

The RPD designation qualifies the company for a possible Priority Review Voucher (PRV) if Seclidemstat is approved. A PRV could generate over $100 million in value on the resale market once granted.

Exhibit 17: Companies that have received PRVs

Date Voucher Awarded	Company Voucher	Held or Sold	Status
2014	BioMarin	Sold July 2014 to Sanofi $67M	Redeemed
2015	United Therapeutics	Sold August 2015 to AbbVie $350M	Redeemed
2015	Asklepion Pharmaceutics	Transferred to Retrophon and Sold May 2015 to Sanofi $245M	Redeemed
2015	Wellstat Therapeutics	Transferred to AstraZeneca	Unused
2015	Alexion Pharmaceuticals	Held	Redeemed
2015	Alexion Pharmaceuticals	Held	Unused
2016	Sarepta Therapeutics	Sold February 2017 to Gilead for $125M	Redeemed
2016	Ionis Pharmaceuticals	Held	Unused
2017	Marathon Pharmaceuticals	Held	Unused
2017	BioMarin	Sold November 2017 for $125M	Unused
2017	Novartis	Held	Redeemed
2017	Ultragenyx Pharmaceutical	Sold December 2017 to Novartis $130M	Redeemed
2017	Spark Therapeutics	Sold April 2018 to Jazz $110M	Unused
2018	Ultragenyx	Sold July 2018 for $81M	Unused
2018	GW Pharma	Sold March 2019 to Biohaven for $105M	Unused
2018	Leadiant Bioscience Inc.	Held	Unused
2018	Sobi and Novimmune	Sold August 2019 to Astra Zeneca for $95M	Unused
2019	Vertex	Held	Unused
2019	Alexion	Held	Unused
2019	Novartis	Held	Unused

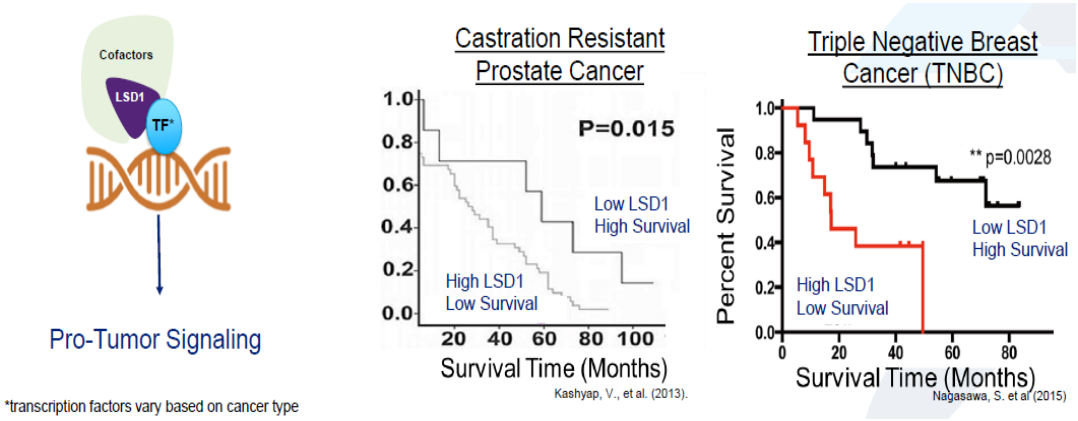
Average PRV value: $144M Median PRV value: $118M

Source: Diamond Equity Research, Salarius Corporate Presentation

Salarius is also targeting ASTs in parallel and is studying Seclidemstat in a second Phase 1 trial (NCT03895684). This, together with Ewing sarcoma, increases the combined market potential. LSD1 associated with several proteins to drive tumor growth. High LSD1 expression is correlated with poor patient prognosis (Exhibit 18), validated LSD1 as an important therapeutic target. A Seclidemstat analog (SP2509) has shown promising single-agent preclinical efficacy in triple-negative breast cancer models and can potentially be combined with other targeted agents for increased activity (Exhibit 19).

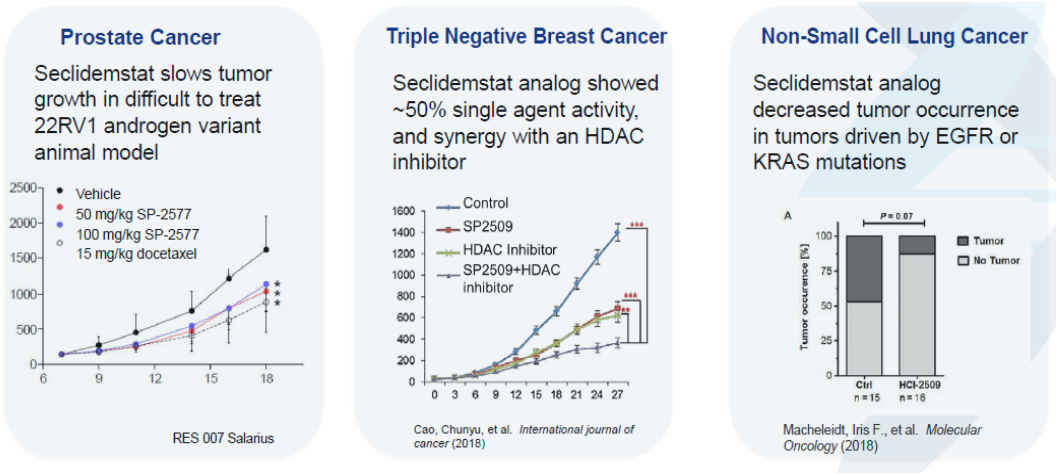
Exhibit 18: Clinical data shows that high levels of LSD1 are associated with poorer patient prognosis

Salarius' has an expanded market opportunity, as it is focusing on Ewing sarcoma and ASTs, simultaneously



Source: Diamond Equity Research, Salarius Corporate Presentation, October 2019

Exhibit 19: Seclidemstat analog shows significant single-agent activity in hard-to-treat triple-negative breast cancer animal model



Source: Diamond Equity Research, Salarius Corporate Presentation, October 2019

As the AST trial is in the dose-escalation phase, we will assign a target market size after the initial data readouts are released (scheduled for 2020). This ongoing work could further strengthen Seclidemstat's pipeline and increase its overall value.

LSD1 Immunotherapy Applications

Immunotherapy has added a novel treatment option for cancer patients, however overall response to immunotherapy can be low for certain cancer patients. As such, new treatment strategies are required to overcome immunotherapy resistance[5]. Recent research published in Oncogene, suggests that epigenetic reprogramming by modulating histone regulation could potentially enhance effector T Lymphocytes trafficking and improve therapeutic efficacy of checkpoint blockades in breast cancer, specifically in triple-negative breast cancer. This research suggests a "negative correlation between expression of LSD1 and immune regulatory genes in TNBC specimens". There is a tremendous opportunity for enhancing or reigniting sensitivity to anti-PD-1 therapy in cancers with low initial response, such as triple-negative breast cancer (TNBC). Fewer than 20% of TNBC patients respond to checkpoint inhibitors. Preclinical work in this area shows combining SP-2509 with anti-PD-1 significantly increased T cell infiltration and suppressed tumor growth and pulmonary metastasis compared to anti-PD-1 therapy alone (Qin. Y, et al.,). Overall, these results suggest that LSD1 inhibition may be an effective combination strategy with immunotherapy as a treatment option for poorly immunogenic breast tumors with Seclidemestat potentially increasing tumor immunogenicity and influencing T cell infiltration[6].

LSD1 inhibition can potentially sensitize tumors to checkpoint inhibitors, although research is still early stage in this area

Third party work also demonstrated that LSD1 inhibition has the potential to turn immuno-suppressed ("cold") tumor microenvironments into immuno-responsive ("hot") microenvironments by silencing the expression of proteins that interfere with T cell infiltration and result in resistance to checkpoint blockade therapy[7] As such, LSD1 inhibition may be a viable therapeutic option for patients with poor response to anti-PD-1 (immune refractory patients). The majority of patients do not respond to checkpoint inhibition (with recent research indicating only 12.5% likely to be responsive[8]), so agents that can sensitize to checkpoint inhibitors are attracting a lot of attention and could present large opportunity for investors with the checkpoint market size projected to reach $29.3 billion by 2023[9].

LSD1 inhibition may be a viable therapeutic option for patients with poor response to anti-PD-1.

Salarius could potentially identify patients who have an increased chance of response given advanced mutations which make patients more prone to LSD1 inhibition. Researchers have recently found that LSD1 is among the most highly expressed histone modifiers in ovarian cancer and that small cell carcinoma of the ovary hypercalcemic type (SCCOHT) cell lines are highly sensitive to reversible LSD1

[5] Qin, Ye, et al. "Inhibition of Histone Lysine-Specific Demethylase 1 Elicits Breast Tumor Immunity and Enhances Antitumor Efficacy of Immune Checkpoint Blockade." Nature News, Nature Publishing Group, 15 Aug. 2018, www.nature.com/articles/s41388-018-0451-5.
[6] Salarius November 2019 Investment Presentation
[7] Sheng, Wanqiang, et al. "LSD1 Ablation Stimulates Anti-Tumor Immunity and Enables Checkpoint Blockade." Cell, U.S. National Library of Medicine, 26 July 2018, www.ncbi.nlm.nih.gov/pubmed/29937226.
[8] Haslam, Alyson, and Vinay Prasad. "Estimation of the Percentage of US Patients with Cancer Who Are Eligible for and Respond to Checkpoint Inhibitor Immunotherapy Drugs." JAMA Network Open, American Medical Association, 3 May 2019, www.ncbi.nlm.nih.gov/pmc/articles/PMC6503493/.
[9] Barton, Cheryl Lee. "Checkpoint Inhibitors: Global Markets." Checkpoint Inhibitors Market Size, Share & Industry Report, www.bccresearch.com/market-research/pharmaceuticals/checkpoint-inhibitors-global-markets.html.

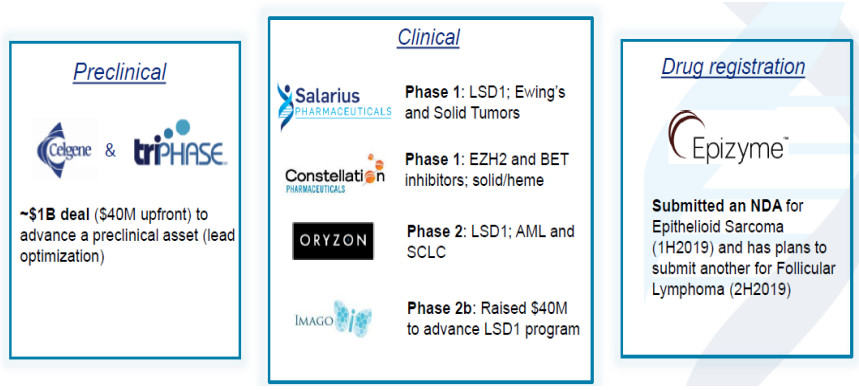
inhibition through stimulation of NF-dependent anti-tumor immunity[10]. Data show that SP-2509 promotes ERV-mediated immune response in SCCOHT cell lines and stimulates T cell infiltration that may be a viable treatment option for this rare ovarian cancer when combined with anti-PD-1 monoclonal antibodies. *Overall there appear to be numerous opportunities for Salarius within immunotherapy, however we note the early stage of this opportunity, with in vitro and in vivo studies underway by Salarius to select checkpoint combination choices for potential clinical trials.*

Salarius' Competitive Landscape

The epigenetic space has seen increased activity in recent years. For instance, Epizyme has submitted a new drug application (NDA) for epithelioid sarcoma and plans to submit one for follicular lymphoma. Other epigenetic-focused companies, like Constellation Pharmaceuticals, are progressing several epigenetic drugs through clinic and their recent increase in valuations reflects their successful progress.

Within the LSD1 space, there are several companies developing inhibitors both in the clinical and preclinical space. Recent clinical data suggests that inhibition of LSD1 may cause beneficial therapeutic responses in cancer patients, giving more confidence to the potential of LSD1 inhibitors as cancer therapies.

Exhibit 20: Current Clinical Landscape



Source: Salarius Corporate Presentation, October 2019

Seclidemstat as a differentiated inhibitor

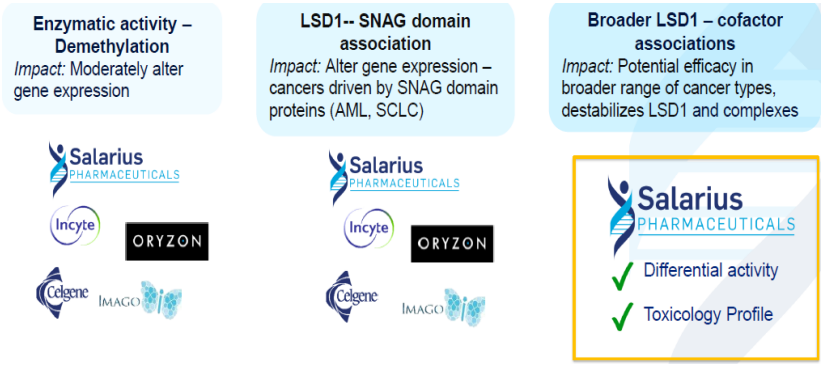
Seclidemstat is differentiated from other LSD1 inhibitors in the clinical stage by being a reversible LSD1 inhibitor that interrupts both the enzymatic and scaffolding activities of LSD1. Seclidemstat is earlier in development than some of the other

Salarius' lead candidate Seclidemstat is a reversible LSD1 inhibitor, targeting LSD1

[10] Soldi, Raffaella, et al. "Abstract 3869: The Reversible LSD1 Inhibitor SP-2509 Promotes Anti-Tumor Immunity in Small Cell Carcinoma of the C Hypercalcemic Type (SCCOHT)." Cancer Research, American Association for Cancer Research, 1 July 2019, cancerres.aacrjournals.org/content/79/13_Supplement/3869.

LSD1 inhibitors but should have important clinical readouts in 2020 for both its Ewing sarcoma and Advanced Solid Tumor trial that will position it favorably within the space.

Exhibit 21: Seclidemstat targets multiple aspects of LSD1



Source: Salarius Corporate Presentation, October 2019

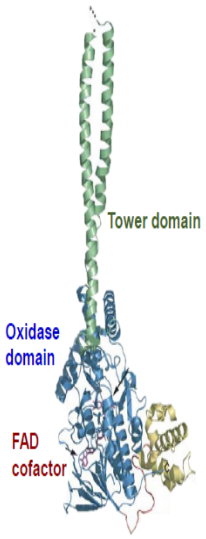
Both, reversible and irreversible inhibitors require more research in a clinical setting to be fully established

Researchers have been actively developing potential LSD1 inhibitors. A few large multinational pharma companies have examined irreversible LSD1 inhibitors in clinical studies. Irreversible LSD1 inhibitors generally cause hematological toxicity (thrombocytopenia and neutropenia).

Seclidemstat may be effective in reducing cancer cell growth, with no sign of hematological toxicities

Seclidemstat, on the other hand, thoroughly inhibits multiple functions of LSD1 in a reversible manner. Consequently, Seclidemstat shows activity across more cancer types than the irreversible inhibitors, with the potential for a more favorable safety profile. Overall, Seclidemstat provides an effective and less toxic option for Ewing sarcoma and possibly other cancer types.

Exhibit 22: Limited competition in Seclidemstat's target market



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

Source: Salarius Corporate Presentation, October 2019

We list in detail the most relevant competitor therapies, both reversible and irreversible below:

ORY-1001: An irreversible LSD1 inhibitor, currently in Phase 2 clinical studies by Oryzon Genomics. The company has combined LSD1 with 5-azacytadine, targeted at elderly patients with acute myeloid leukemia (AML). This has shown encouraging results (with smaller doses than Phase 1), leading to a reduction in toxicity. However, at least 50% of the trial patients continue to experience grade 3 and/or 4 hematological toxicity.

Numerous companies are targeting LSD1, but very few have developed reversible inhibitor – Salarius has clear differentiator

IMG-7289: This compound (also known as bomedemstat), developed by Imago Biosciences, is an orally available, irreversible LSD1 inhibitor, with potential antineoplastic activity in patients with AML and myelodysplastic syndrome (MDS). The company has completed Phase 1 studies and plans for a study in patients with AML, MDS, and myeloproliferative neoplasms, including myelofibrosis with preliminary data from phase 2 trial for myelofibrosis to be presented at ASH in December 2019.

INCB059872: Developed by Incyte Corporation, this is an irreversible LSD1 inhibitor with potential antineoplastic activity. It is a potent, selective and orally bioavailable FAD-directed inhibitor of LSD1 entering Phase 1/2 clinical development. The company targets patients with AML and Ewing sarcoma, and is in the process of conducting further studies on Ewing sarcoma (Phase 1 to be completed by June 2021).

CC-90011: Celgene's lead compound CC-90011 is probably only the second reversible inhibitor of LSD1 (other than Seclidemstat) in Phase 1 study in the clinical stage. This inhibitor is targeted at treating small-cell lung cancer (NCT03850067) and solid tumors and non-hodgkin's lymphomas (NCT02875223).

BEA 17: This preclinical compound, developed by Swedish drug Company Beactica AB, targets therapies for glioblastoma, an aggressive form of brain cancer. It is a reversible LSD1 modulator and has shown efficacy in models of treatment-resistant glioblastoma. The company recently received a grant of USD300,000 from SweLife and Medtech4Health for further study.

RASP-201: Rasna Therapeutics, a U.S. biotechnology company, is developing a reversible LSD1 modulator compound to target AML. The compound is in the pre-clinical stage.

HM9XXX Series: Hanmi Pharmaceutical, a South Korea-based pharmaceutical company, is developing a reversible LSD1 modulator compound (codenamed HNMXXX Series) to target small-cell lung cancer and AML. This compound is in the pre-clinical stage.

Seclidemstat's competitive advantage

- Seclidemstat has been found to be more effective in reducing certain cancer cell type proliferation/viability than competitors
- According to data so far, it has a superior hematological safety profile (no sign of hematological toxicities associated with other LSD1 inhibitors)
- It seems to be the only LSD1 inhibitor that has shown the ability to promote LSD1 degradation
- It is able to inhibit LSD1 association with a much broader set of proteins, resulting in efficacy across many more cancers (e.g. late stage prostate, breast, and ovarian cancer)
- Salarius has a U.S. patent for the drug covering it until 2031 (exclusive of all possible extensions).

Salarius has patents covering Seclidemstat until 2032

Valuation

It is challenging to value Salarius given its early stage and the limited number of similar publicly traded epigenetic focused oncology biotechnology companies. In our technology value analysis, we screened for small-capitalization clinical-stage oncology companies in the sector. We used a blend of these companies to arrive at a median technology value which we then additionally discounted at 30% given Salarius' earlier stage than some of the companies. Our technology value model yielded a per share value of $10 per share, which is obviously dependent on the technology proving efficacious.

Technology Value Analysis

Small Capitalization Clinical-stage Oncology Biotech Companies							
Ticker	Company Name	Market Cap (MM)	Cash & Cash Equivalent (MM)	Technology Value(MM)	Stage of Latest Drug	Drug Technologies	Tech Value per Drug
ORY.MC	Oryzon Genomics S.A.	135.36	41.94	93.42	Phase 2	3	31.14
CNST	Constellation Pharmaceuticals, Inc.	1543.00	89.07	1453.93	Phase 2	2	726.97
PRQR	ProQR Therapeutics N.V.	268.11	82.27	185.84	Phase 2	3	61.95
PDSB	PDS Biotechnology Corporation	14.90	21.73	-6.83	Phase 1	4	-1.71
ONCS	OncoSec Medical Incorporated	22.84	25.15	-2.31	Phase 2	3	-0.77
APVO	Aptevo Therapeutics Inc.	30.59	17.68	12.91	Phase 1	3	4.30
Mean		*335.80*	*46.31*	*289.49*		*3*	*136.98*
Median		*82.97*	*33.55*	*53.16*		*3*	*17.72*
SLRX	Salarius Pharmaceuticals Inc.	16.27	4.00	12.27	Phase 1	1	12.27

Source: Diamond Equity Research, company filings

Technology Value Analysis	
Enterprise Value	$ 53,162,000
Add: Cash and Equivalents	$ 3,999,676
Less: Total Debt	$ -
Equity Value	$ 57,161,676
Outstanding Shares	4,068,520
Valuation Per Share	**$ 10**

Source: Diamond Equity Research, company filings

Given the uniqueness of Salarius' business model and the limited number of public companies to compare it with, we built a standalone discounted cash flow analysis to value the business (refer to the Appendix for our assumptions). Given that Salarius has a limited operating history, we built a bottom-up model to value the business, projecting sales based on the number of patients with Ewing sarcoma and Advanced Solid Tumors who received the company's lead drug candidate Seclidemstat and the annual cost of Seclidemstat per patient. Our discounted cash flow model indicates a fair value of $6 per share, which is dependent on successful results within Ewing Sarcoma.

SLRX : Discounted Cash Flow

$'000	FY17A	FY18A	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E
Operating Income (EBIT)	(1,749)	(1,685)	(7,794)	(6,644)	(12,203)	(16,437)	(18,081)	16,520
Less: CAPEX	0	0	67	180	66	66	0	1,101
Add: D & A	17	17	250	300	366	447	545	665
Current Assets excl. cash	135	3,153	2,661	4,020	1,474	1,474	0	6,608
Less: Current Liabilities	1,722	7,885	3,976	8,359	6,507	6,904	7,594	21,863
Working Capital	(1,587)	(4,732)	(1,315)	(4,339)	(5,033)	(5,430)	(7,594)	(15,256)
Increase/ (Decrease) in Working Capital:		(3,145)	3,417	(3,024)	(694)	(396)	(2,164)	(7,662)
Less: Taxes	0	0	0	0	0	0	0	4,183
Free Cash Flow for the Firm/Equity =	**(1,732)**	**1,477**	**(11,028)**	**(3,501)**	**(11,209)**	**(15,660)**	**(15,372)**	**19,562**
Terminal Value =								**122,396**
Present Value of Free Cash Flows =			**(10,548)**	**(2,803)**	**(7,513)**	**(8,786)**	**(7,219)**	**55,809**

Source: Diamond Equity Research, Company filings

($ in thousands except per Share data)	
Total Present Value of Free Cash Flows =	**18,939**
Add: Cash & cash equivalents =	4,000
Less: PV of Total Debt o/s (latest filings) =	0
Less: Preferred Shares	0
Less: Minority Interest	0
Equity Value (Present Value) =	**22,939**
Number of Shares outstanding (in thousands)=	4,069
DCF Value per Share ($)=	**6**
Technology Analysis Value per Share ($)=	**10**
Risk Adjusted PV PRV Value	**1**
Combined Value per Share ($)=	**9**

Source: Diamond Equity Research, Company filings

Given the inherent assumptions in the valuation models, we chose to use an average of our discounted cash flow valuation and our comparable company analysis valuation. We arrive at a blended valuation of $9 per share.

Based on our analysis on phase 1 Pharma acquisitions and R&D collaborations in the recent five years, Salarius could become a potential acquisition target with much higher enterprise value *if* their Phase 1 Ewing sarcoma trail is successful with positive results out in 2020.[11] *We also include a heavily risk adjusted per share value for a potential PRV sale in line with historical transactions on a potential Ewing approval.*

[11] Based on average deal value. See Appendix B

Experienced Management Team

Salarius' management team brings more than a decade of experience in growing established businesses and start-ups in the pharmaceutical industry.

David J. Arthur (President, Chief Executive Officer): David Arthur is a senior life science executive with more than 25 years of global experience in building and leading medical and marketing organizations. He specializes in product development and managing pharmaceutical companies. Prior to Salarius, he was managing director of Dacon Pharma, LLC. He spent more than two decades with Eli Lilly and Boehringer-Ingelheim in various executive capacities, managing products and driving business development and assisting with financial planing. He holds a B.S. in Chemical Engineering from North Carolina State University and a Master of Business Administration from Duke University's Fuqua School of Business.

David Arthur is an experienced life science professional and has extensive expertise in building and leading healthcare organizations

Scott Jordan (Chief Business Officer): Mr. Jordan has served as the company's Chief Business Officer since September 2019 and was Salarius' Chief Financial Officer from the completion of the Merger until September 10th, 2019. Prior to completion of the Merger, he served as Chief Financial Officer of Private Salarius. Mr. Jordan is an accomplished life sciences professional with abundant experience in investment banking and pharmaceutical business development. From July 2016 to August 2018, he served as Chief Financial Officer of Beta Cat Pharmaceuticals, Inc., a biotechnology company, and from 2018 to present as chief investment officer of Stingray Therapeutics, a biotechnology therapeutics company. Prior to that, Mr. Jordan served as co-founder and advisor at Healthios Xchange, an online investment marketplace from 2013 to 2016, and from 2010 to 2013 served as vice president of Healthios Capital Markets, LLC, a healthcare investment bank. Mr. Jordan earned a B.A. in Marketing from Michigan State University and an M.B.A. from Kellstadt Graduate School of Management (DePaul).

Dr. Horrigan has strong research capability in the areas of cellular control mechanisms of cancer and developing therapeutics using biomarkers

Mark J. Rosenblum (Chief Financial Officer): Mark Rosenblum is a financial executive with more than three decades of senior management experience, mostly within the healthcare sector. Most recently, he served as chairman, CEO and director of ActiveCare. Previously, he was CFO of Advaxis. He left Wellman (DAK Americas) as chief accounting officer, after spending close to two decades with the company in various capacities most recently as Chief Accounting Officer. He began his career with Deloitte. He holds a Master's in Accountancy and a B.S. in Accounting from the University of South Carolina and is a Certified Public Accountant.

Dr. Stephen Horrigan, PhD (Chief Scientific Officer): Stephen Horrigan is a molecular geneticist, known for developing pioneering methods to enhance drug discovery using genomic profiles and biomarkers. He has worked with various research organizations on internal and collaborative research programs. He has expertise in the cellular control mechanisms of cancer and in the discovery and development of therapeutics (using biomarkers). He has several publications and patents in this field to his credit. He was associate professor at Georgetown University Medical Center's Department of Pediatrics and Lombardi Cancer Center, and held similar positions at the University of Illinois and the University of Chicago. We view Dr. Horrigan's involvement with Salarius as an important scientific strength given his significant scientific achievements in the field of cancer research.

Margaret Dugan, MD (Senior Medical Advisor): Dr. Dugan is a consultant to Salarius and is also a board-certified medical oncologist and hematologist from the New York University Fellowship Program, holding an MD from New York University School of Medicine. Dr. Dugan holds experience working at larger pharmaceutical companies such as American Cyanamid Co (now part of Merck) and Novartis Pharmaceuticals. Dr. Dugan worked in previous roles to help secure approval for oncology products and we view her advisor role as strengthening the scientific depth of Salarius management.

Salarius also brings an experienced board of directors and a strong advisory team working together with the executive team to develop targeted therapies

Risk Factors

- Salarius' candidate products are still in their early stages of clinical development, and subsequent clinical research may take years and require substantial expenditures and even if financed the results may ultimately prove unsuccessful.
- Ewing Sarcoma phase 1 trial human data may not prove successful or not be as the company anticipates. Current data is based on animal studies.
- Reliance on government funding for its programs may add uncertainty to the company's research and commercialization efforts.
- The company is highly dependent on management and its advisors. Therefore, a loss of service of senior management or key employees could harm its ability to develop and commercialize its product candidates given the company's smaller size.
- Salarius relies on patents for its product candidates and any future product candidates. It may not be able to compete effectively if its intellectual property proves insufficient.
- The company's lead candidates, if approved, will likely face competition within the pharmaceutical industry. Although it is focused on a specific therapy, close competition could lead to reduced market share for its product candidates and put downward pressure on pricing, harming the company's business, financial position, operating results, and prospects.
- As a newly public and small company, Salarius will spend substantial time and significant amounts of funding to comply with public company regulations and maintain effective internal controls.
- The FDA's marketing approval process is lengthy, time-consuming, and inherently unpredictable even with the expedited pathway investors will need a long horizon in order to realize profits, albeit with trial/data milestones over that period if Salarius is successful.
- The company will require additional financing to successfully commercialize its pipeline, there is no assurance the company can raise financing or that the financing will be at attractive terms.
- Salarius currently is underfollowed by sell-side and investors and has very low trading volume, this could limit investors ability to increase their ownership or sell some of their positions.
- Company has incurred losses since its inception, and significant further operating losses are expected in foreseeable future. The company may never generate profits.
- The company's future revenue is dependent on market acceptance, pricing, reimbursement and numerous other difficult to estimate factors.

This list of risk factors is not comprehensive. For a full list, please refer to Salarius' latest prospectus and/or annual filings.

Appendix

Pediatric Priority Review Voucher Value

Appendix A. Seclidemstat Is Eligible To Receive A Pediatric Priority Review Voucher (PRV) Upon Ewing Approval, ~$100M Value

Date Voucher Awarded	Company Voucher	Held or Sold	Status
2014	BioMarin	Sold July 2014 to Sanofi $67M	Redeemed
2015	United Therapeutics	Sold August 2015 to AbbVie $350M	Redeemed
2015	Asklepion Pharmaceutics	Transferred to Retrophon and Sold May 2015 to Sanofi $245M	Redeemed
2015	Wellstat Therapeutics	Transferred to AstraZeneca	Unused
2015	Alexion Pharmaceuticals	Held	Redeemed
2015	Alexion Pharmaceuticals	Held	Unused
2016	Sarepta Therapeutics	Sold February 2017 to Gilead for $125M	Redeemed
2016	Ionis Pharmaceuticals	Held	Unused
2017	Marathon Pharmaceuticals	Held	Unused
2017	BioMarin	Sold November 2017 for $125M	Unused
2017	Novartis	Held	Redeemed
2017	Ultragenyx Pharmaceutical	Sold December 2017 to Novartis $130M	Redeemed
2017	Spark Therapeutics	Sold April 2018 to Jazz $110M	Unused
2018	Ultragenyx	Sold July 2018 for $81M	Unused
2018	GW Pharma	Sold March 2019 to Biohaven for $105M	Unused
2018	Leadiant Bioscience Inc.	Held	Unused
2018	Sobi and Novimmune	Sold August 2019 to Astra Zeneca for $95M	Unused
2019	Vertex	Held	Unused
2019	Alexion	Held	Unused
2019	Novartis	Held	Unused

Average PRV value: $144M Median PRV value: $118M

Source: Salarius Pharmaceuticals, 2019 Corporate Presentation

Phase 1 Pharma Acquisitions and R&D Collaborations

Phase 1 Pharma Acquisitions and R&D Collaborations						
Year	Aquiror	Target Company	Target Company Country	Upfront Deal Value ($mn)	Total Deal Value ($mn)	Lead Asset Stage At Acquisition
2014	Merck	OncoEthix	Switzerland	110	375	1
2014	Roche	Seragon	U.S.	725	1,725	1
2014	Roche	Santaris	Denmark	250	450	1
2016	Novartis*	Cerulean Pharma	U.S.	5	1,200	1
2016	Gilead Sciences	Nimbus Apollo	US	400	1,200	1
2016	Incyte*	Merus	Netherlands	120	3,000	Preclinical
2016	Roche	Tensha	U.S.	115	535	1
2016	Celldex Therapeutics Inc	Koltan Pharmaceuticals	U.S.	62	125	1
2017	Bristol-Myers Squibb (BMS)*	CytomX Therapeutics	U.S.	200	1,242	1
2017	Gilead	Cell Design Labs	U.S.	175	567	1
2017	Merck	Rigontec GmbH	Germany	137	416	1
2018	Takeda Pharmaceutical*	Denali Therapeutics	U.S.	45	1,173	1
2018	Roche	Tusk Therapeutics	UK	81	758	1
2018	Janssen	BeneVir Biopharm	U.S.	140	1,000	1
2019	AbbVie*	Voyager Therapeutics	U.S.	65	1,179	1
2019	Pfizer	Therachon	Switzerland	340	810	1

*Collaborative R&D Deal

Source: Diamond Equity Research

Income Statement Projections

SLRX : P&L FY Ends on December 31										
$ '000	FY17A	FY18A	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E
REVENUE	**1,852**	**1,951**	**3,326**	**6,000**	**2,200**	**0**	**0**	**55,066**	**66,500**	**132,406**
Revenue from Seclidemstat (Ewing Sarcoma)							**0**	**52,250**	**66,500**	**66,500**
Revenue from Seclidemstat (Prostate Advanced Solid Tumors)										**65,906**
Grant Revenue	**1851.89**	**1,951**	**3,326**	**6,000**	**2,200**	**0**	**0**	**0**	**0**	**0**
ROW Income								**2,816**	**5,065**	**12,280**
Cost of goods sold								(13,767)	(14,313)	(28,937)
Gross Profit	**1,852**	**1,951**	**3,326**	**6,000**	**2,200**	**0**	**0**	**41,300**	**52,187**	**103,469**
Research and development expenses	(2,130)	(1,288)	(4,120)	(4,944)	(5,933)	(7,120)	(7,832)	(5,507)	(5,320)	(6,620)
General and administrative expenses	(1,471)	(2,348)	(7,000)	(7,700)	(8,470)	(9,317)	(10,249)	(11,013)	(9,975)	(11,917)
Selling and marketing expenses							0	(8,260)	(9,975)	(19,861)
Total Operating Costs & Expenses	**(3,601)**	**(3,636)**	**(11,120)**	**(12,644)**	**(14,403)**	**(16,437)**	**(18,081)**	**(24,780)**	**(25,270)**	**(38,398)**
Interest income	2	15	26	195	199	203	207	211	215	220
Adj. PBT	**(1,747)**	**(1,670)**	**(7,768)**	**(6,449)**	**(12,004)**	**(16,234)**	**(17,874)**	**16,731**	**27,132**	**65,291**
Income Tax Expenses (Benefits)	0	0	0	0	0	0	0	4,183	6,783	16,323
Adj. Net Profit/(Loss) from Continuing operations	**(1,747)**	**(1,670)**	**(7,768)**	**(6,449)**	**(12,004)**	**(16,234)**	**(17,874)**	**12,548**	**20,349**	**48,968**
Adj. Net Income Attributable To Common Shareholders	**(1,747)**	**(1,670)**	**(7,768)**	**(6,449)**	**(12,004)**	**(16,234)**	**(17,874)**	**12,548**	**20,349**	**48,968**
Earnings per Share (Adjusted) from Cont Ops (in $)										
Basic	-	-	(1.98)	(0.88)	(1.17)	(1.22)	(1.17)	0.79	1.25	2.91
Diluted	-	-	(1.98)	(0.88)	(1.17)	(1.22)	(1.17)	0.79	1.25	2.91
Total Earnings per Share (Adjusted)										
Basic	-	-	(1.98)	(0.88)	(1.17)	(1.22)	(1.17)	0.79	1.25	2.91
Diluted	-	-	(1.98)	(0.88)	(1.17)	(1.22)	(1.17)	0.79	1.25	2.91
Weighted Average no. of Shares outstanding										
Basic	N/A	N/A	3,928	7,300	10,300	13,300	15,300	15,800	16,300	16,800
Diluted	N/A	N/A	3,928	7,300	10,300	13,300	15,300	15,800	16,300	16,800

Source: Company filings, Diamond Equity Research

Assumptions Used in Salarius Financial Model

Revenue

Salarius is a clinical-stage biotechnology company developing its lead product Seclidemstat as a potential novel treatment of Ewing sarcoma and Advanced Solid Tumors such as Prostate cancer. In line with its current strategy, the company-initiated phase I trials in Ewing sarcoma in 2018 and Advanced Solid Tumors in 2019 respectively. With this timeline, we assume Salarius files a new drug application in mid- to late 2022, we model Salarius launching its lead product for the treatment of Ewing sarcoma in 2024 and Advanced Solid Tumors for Prostate Cancer in 2026 if clinical results are positive and FDA approval is secured, noting there is opportunity to expand internationally. According to the Sarcoma Foundation of America, incidence of Ewing sarcoma is less than 500 cases diagnosed annually in the United States with no significant increase. We expect 500 patients in the U.S. to be suffering from Ewing sarcoma during the year 2024 to 2026. We forecast 55% of market penetration initially to 70% in 2026, as there were no other treatment options at time. We assume penetration of the market improves as the company increases its sales and marketing efforts. We conservatively assume ROW revenue as 25% of U.S. net income over forecast period. The latest market studies shared by IQVIA helped us to calculate the unit sale price: we forecast pricing of $200,000 per year per patient until 2026. We project revenue of $3.3 million in FY19 from grants and project revenue from Seclidemstat targeting Ewing sarcoma Patients of $52 million in FY24 and $67 million in FY25, contingent on approval and successful commercialization of Seclidemstat for Ewing sarcoma. In our model Seclidemstat for treatment of Advanced Solid Tumors for Prostate Cancer will be launched in 2026, generating revenue of $66 million in FY26. *We note our model requires many assumptions, which investors can modify based on their expectations and overall risk assessment given the early stage of company.*

Revenue Model

SLRX : Operating Metrics									
Market Metrics ($ in '000)	**FY18A**	**FY19E**	**FY20E**	**FY21E**	**FY22E**	**FY23E**	**FY24E**	**FY25E**	**FY26E**
We've assumed that Seclidemstat is launched in the United States for Treatment of Ewing Sarcoma in 2024 and for Advanced Solid Tumors Targeting Prostate Cancer in 2026									
Seclidemstat Drug									
For Ewing Sarcoma									
U.S. Patients	500	500	500	500	500	500	500	500	500
% Market Achieved							*55.0%*	*70.0%*	*70.0%*
Patients receiving Seclidemstat							**275**	**350**	**350**
Annual Treatment Cost per patient							$200	$200	$200
% Reimbursed							95.0%	95.0%	95.0%
Revenue from Seclidemstat (Ewing Sarcoma)						**$0**	**$52,250**	**$66,500**	**$66,500**
For Advanced Solid Tumors (Prostate Cancer)									
U.S. Patients	30,000	30,600	31,212	31,836	32,473	33,122	33,785	34,461	35,150
% Market Achieved									*1.3%*
Patients received Seclidemstat									**439**
Annual Treatment Cost per patient									$200
% Reimbursed									75.0%
Revenue from Seclidemstat (Advanced Solid Tumors)									**$65,906**
ROW Income							**$2,816**	**$5,065**	**$12,280**
Total Revenue from Seclidemstat							**$55,066**	**$71,565**	**$144,686**
Grant Revenue	$1,951	$3,326	$6,000	$2,200					
Total Revenue	**$1,951**	**$3,326**	**$6,000**	**$2,200**	**$0**	**$0**	**$55,066**	**$71,565**	**$144,686**
Gross Margin (as % of sales)	-	-	-	-	-	75.0%	75.0%	80.0%	80.0%
Cost of goods sold	-	-	-	-	-	$0	$13,767	$14,313	$28,937

Source: Diamond Equity Research

Gross Margins

This model assumes gross margin to be very close to 80% by FY26, in line with other small molecules. The model assumes a slightly lower margin for the first two years, discounting for the uncertainty surrounding initial negotiations of terms with third-party manufacturers. Our assumptions for each year are outlined below:

Gross margin

Period	Rate
FY24	75.0%
FY25	80.0%
FY26	80.0%

Operating Expenses

i. General and administrative (G&A) expenses

Assumptions for G&A expenses are based on the expectation that Salarius will start spending on sales and marketing efforts in 2024 after the commercialization of Seclidemstat. G&A costs are also likely to rise as the company manages rapid growth in revenue. We model G&A expenses of around 9% of sales by FY26.

G&A expenses (USD'000s)

Period	Assumption
FY19	7,000
FY20	7,700
FY21	8,470
FY22	9,317
FY23	10,249
FY24	10,450
FY25	9,975
FY26	11,917

ii. Research and development (R&D) expenses

Salarius has incurred significant R&D expenses in the past, and we expect it to continue to do so given the number of potential disruptive technologies in its pipeline that could expand its drug portfolio. We believe it will need to incur sizeable costs to complete clinical trials for Seclidemstat. Based on its interim analysis, it plans to pursue rounds of financing in the near term. Although it expects R&D expenses to grow, R&D expenses as a percentage of sales should decline: we model expenses at around 10% of sales in 2024 and just 5% in 2026, primarily due to revenue growth projections.

R&D expenses (USD'000s)

Period	Assumption
FY19	4,120
FY20	4,944
FY21	5,933
FY22	7,120
FY23	7,832
FY24	5,225
FY25	5,320
FY26	6,620

Tax rate:
From FY24, we assume an effective tax rate of 25%.

Short-term debt:
In our model, we assume that the company will raise funds primarily via short-term debt and equity offerings.

WACC in DCF:

Risk premium: We use the S&P Biotechnology Select Industry Index as the best proxy for the market index for Salarius. We also incorporate a 4% size premium conservatively given the microcap nature of the stock.

- Risk-free rate: We use the ten-year US Treasury rate
- Beta: 1.38, based on the average for the comparable biotechnology companies
- Cost of debt: We assume an interest rate on debt of 10%, in line with our assumption of common stock issuances to meet working capital requirements
- Long-term growth rate: We assume a long-term growth rate of 3% for terminal value

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