

Company Sponsored Research  
Update Note  
05/21/2020

# Salarius Pharmaceuticals Inc.

## (NASDAQ: SLRX)

**Numerous Upcoming Clinical Milestones with Limited COVID-19 Disruption to Date**

### Investment Highlights:

- Salarius Pharmaceuticals advanced dose escalation in Ewing Sarcoma trial with early stage clinical readouts in 2020.** The company reached the sixth level dosing cohort in its phase 1/2 study of Seclidemstat in Ewing sarcoma upon the Safety Committee Review. Seclidemstat has received the Fast Track Designation by FDA for relapsed or refractory Ewing sarcoma. The company previously has received Orphan Drug Designation and Rare Pediatric Disease Designation, which should position Salarius for expedited FDA drug development and review processes. The company expects to reach the Maximum Tolerated Dose (MTD) in mid-2020. Salarius Pharmaceuticals anticipates releasing data from its Ewing sarcoma clinical trial and second clinical trial in advanced solid tumors (AST) in 2020, which we view as key inflection points for the stock.
- Financings provide runway to inflection points.** Recent public offering of \$11 million gross proceeds should provide the company runway to second half of 2021 and allow it to reach key data readouts. The company ended the quarter with \$9.65 million in cash and cash equivalents and has up to \$9.1 million of non-dilutive financing available from Cancer Prevention and Research Institute of Texas (CPRIT).
- COVID-19 has not materially interrupted business.** To date there have been minimal interruptions in Salarius' operations including the Seclidemstat trials, however we note this might change given the ever-evolving situation and management has guided they will communicate material changes to shareholders.
- Strengthened IP portfolio with company exploring checkpoint inhibitor applications.** Recent paper titled "The novel reversible LSD1 inhibitor SP-2577 promotes anti-tumor immunity in SWIthc/Sucrose-NonFermentable (SWI/SNF) complex mutated ovarian cancer" was published on bioRxiv.com demonstrating potential for seclidemstat to be used in combination with checkpoint inhibitors (market projected to be \$29.3 billion by 2023<sup>1</sup>). Salarius continued to strengthen its IP around Seclidemstat, now holding over 22 patents in U.S. and abroad and has 11 pending applications. These patents and patent applications relate to Seclidemstat or structurally similar compounds, which we view as strengthening the overall potential commercialization opportunities of Salarius, assuming efficacy data around Seclidemstat.
- Small capitalization life science equities tend to trade on fundamentals of their business and trial results more than macro issues.** As such, we view the upside potential of the stock much more dependent on their upcoming trial data in the growing epigenetics sector, versus macroeconomic headwinds. Given the early stage of the company, investment is suited for sophisticated institutional investors or high-risk tolerant retail investors in our view. Our valuation model indicates a fair value of \$4.50 per share, which is contingent on positive phase 1/2 trial results in Ewing sarcoma.

### Company Description

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

1-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.

### Biotechnology

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### Price- Volume History



Source: Yahoofinance

### Key Statistics

Closing Price (As of 05/20/2020)	\$1.24
52 Week Range	\$0.55-\$24.45
Average Daily Volume	375,565
Shares Outstanding (M)	13.66
Market Capitalization (M)	16.94
Number of Analysts Covering	2
Valuation Per Share	\$4.50
Enterprise Value/Revenue	N/A

### Revenue(\$ in millions)

Dec. FY	2018A	2019A	2020E
FY	1.95A	3.47A	5.50E

### EPS(\$)

Dec. FY	2018A	2019A	2020E
FY	(1.16)A	(2.12)A	(0.88)E

## First Quarter 2020 Results

For the first quarter ending March 31st, 2020, Salarius Pharmaceuticals reported grant revenue of \$1,132,830, as compared to \$ 655,635 for the same period last year. Total operating expenses were \$3,502,388, compared to \$2,188,419 in Q1 2019 , a 60% increase, primarily due to an increase of \$943,442 in research and development expenses resulting from increased clinical expenses and drug manufacturing costs, and a \$370,527 increase in general and administrative expenses resulting from the company's transformation into a public company and increased personnel expenses. Salarius' net loss for the three months ending March 31st, 2020 was \$2,083,816, or \$0.22 per basic and diluted share, compared to a net loss of \$1,522,076, or \$0.64 per basic and diluted share in year-ago period. We expect research and development expenses to continue to increase, as the company develops its early stage epigenetics pipeline and explores additional indications

## Liquidity and Balance Sheet

As of March 31st, 2020, Salarius' cash and cash equivalents were equal to \$9,646,940, compared to \$3,738,900 as of December 31st, 2019. Total current assets increased by 132% to \$10,884,429 on March 31st, 2020; total liabilities decreased from \$3,313,544 at year-end 2019 to \$2,062,761, with the company having no long-term debt. On February 11th, 2020, Salarius completed a public offering with total gross proceeds of approximately \$11 million, which will be used for general working capital purposes and is expected to fund the company to the second half of 2021 and beyond key clinical data releases that may function as key catalysts for shares. Salarius is also eligible for up to \$9.1 million from CPRIT. *Overall, we view Salarius as well positioned financially to reach critical data readouts this year, which if positive could function to reset their valuation.*

## 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. In some cancer's gene expression is dysregulated and incorrectly turns 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. Salarius is running two Phase 1/2 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 (\$9.1 million available as of December 2019). 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.<sup>1</sup> 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.<sup>2</sup> 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 1/2 trials of Seclidemstat in Ewing sarcoma and Advanced Solid Tumors (AST) with expected readouts in 1H 2020 and 2H 2020. Based on 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 either trial is successful. 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 1/2 Ewing sarcoma or Phase 1/2 AST trial is successful*

<sup>1</sup> Based on average selling price in Salarius Investor Presentation

<sup>2</sup> 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

## 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 to potentially 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.*

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