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Zacks Small-Cap Research

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Brad Sorensen, CFA
312-265-9574
bsorensen@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Salarius Pharma (SLRX-NASDAQ)

SLRX: Company Gains Approval for Phase I Trial

SLRX is a clinical-stage biotechnology company developing treatments for patients with cancer that have few options. We are valuing SLRX at $6.75 per share using the comparable value based on companies with similar characteristics.

Current Price (07/10/23)	$1.45
Valuation	**$6.75**

OUTLOOK

Salarius Pharmaceuticals is a clinical-stage biotechnology company focused on developing treatments for patients that have cancers with few treatment options available. The company is uniquely pursuing two lines of treatment that have the potential to treat a wide range of cancers.

The company recently announced that it has received FDA clearance for a Phase I Clinical Trial for SP-3164 for treatment of Relapsed/Refractory Non-Hodgkin Lymphoma.

SUMMARY DATA

52-Week High	**$6.25**
52-Week Low	**$1.13**
One-Year Return (%)	**-71.76**
Beta	**0.99**
Average Daily Volume (sh)	**40,456**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 E	0 E	0 E	0 E
2024	0 E	0 E	0 E	0 E	0 E
2025	0 E	0 E	0 E	0 E	0 E

Earning per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	N/A	N/A	N/A	N/A	-14.88A
2023	-$2.23 A	-$1.03 E	-$0.87 E	-$0.73 E	-$4.86 E
2024	-$0.65 E	-$0.62 E	-$0.63 E	-$0.62 E	-$2.52 E
2025	-$0.60 E	-$0.55 E	-$0.55 E	-$0.50 E	-$2.20 E

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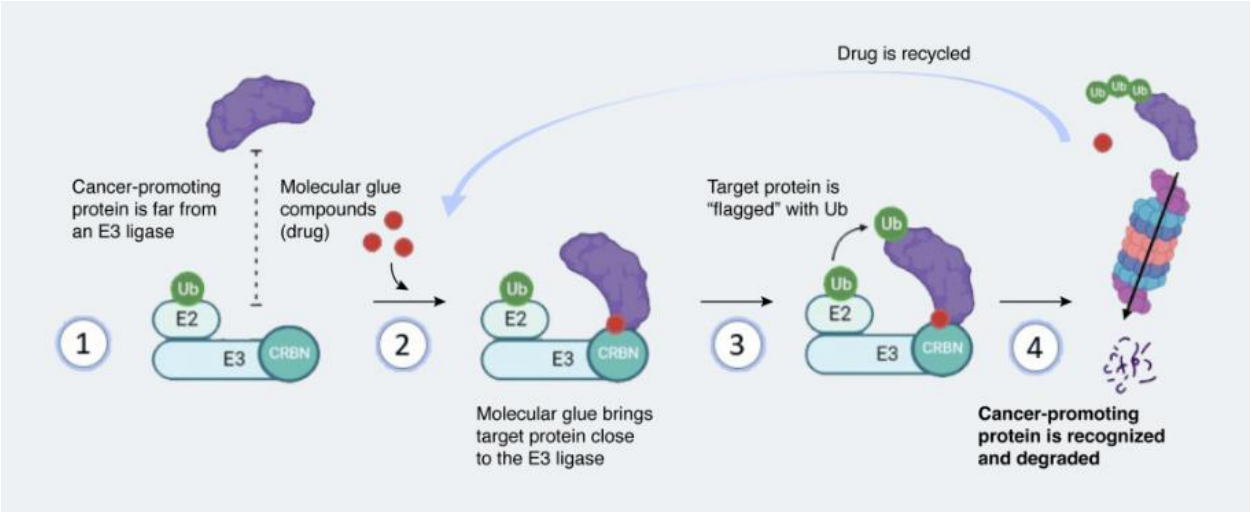
Update

- Salarius announced that it has received FDA clearance of SP-3164 Investigational New Drug Application (NDA) to begin a Phase I clinical trial in relapsed/refractory Non-Hodgkin Lymphoma patients.
    - SP-3164 is explained in more detail below, but this novel targeted protein degrader is one of the compounds being developed by Salarius that we believe had most promise and were quite certain trials would being soon.
        - Patient dosing is expected to begin later this year.

- According to the American Cancer Society, Non-Hodgkin Lymphoma (NHL) accounts for about 4% of all cancers, with the company noting that more than 80,000 new cases of NHL are expected to be diagnosed in the US this year.

- David Arthur, CEO of Salarius, noted that first generation targeted protein degraders generated more than $16 billion in sales in 2021, and that SP-3164, a next generation targeted protein degrader, can build on that success.

Diving into SP-3164 a bit more, as noted, Salarius is developing a next generation targeted protein degrader, also referred to as a molecular glue. Molecular glues are small molecules that take advantage of the body's normal protein degradation process, discussed above, to cause the elimination of cancer-promoting proteins. This occurs because the molecular glue induces proximity of the cancer-promoting protein and an enzyme (E3 ligase) that then allows target proteins to be flagged for degradation and eliminated (see Figure below). Elimination of the cancer-promoting proteins leads to profound therapeutic effects. This is exciting to us, and to potential investors, as it's a market where a product with a similar mechanism of action, Revlimid by Celgene, posted about $10 billion in sales in 2022. Those sales are declining as generics take market share, but the need remains great for a new, improved version of this molecular glue. The company notes that their molecular glue, SP-3164, demonstrates more robust degradation of Ikaros and Aiolos (proteins that can promote cancer growth) compared to Revlimid and resulted in improved tumor growth inhibition in mouse models of cancer.



Source: Salarius Pharmaceuticals, 6/30/2023

As you can see from the image, molecular glue compounds are the key to degrading the cancer-promoting protein and that is what Salarius is focused on—developing new and unique molecular glue protein degraders. Salarius believes that its molecular glue, SP-316, has the potential to impact both hematologic (cancers in the blood) and solid tumors. The company notes that SP-3164's potential has been demonstrated in in vitro studies and in preclinical mouse models of lymphoma and multiple myeloma. According to the company, “SP-3164 treatment showed robust anticancer activity in cells and tumored mouse models. Encouragingly, in lymphoma preclinical mouse models, treatment with SP-3164 combined with a standard of care agent resulted in complete tumor regressions.”

We are also encouraged by the announcement from the company recently that it has completed two Good Laboratory Practice toxicology studies on SP-3164 with no unexpected safety findings during either course of study. There is little doubt that the positive results from these studies contributed to the FDA approval of the Phase I trial.

The approval of the Phase I trial reinforces our belief that Salarius is a company with great potential and two major treatment possibilities that is moving those treatments forward. We reiterate that SLRX is poised to move substantially higher in our view as positive results from trials are announced and urge investors to take a look at SLRX before that jump occurs

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