Zacks Small-Cap Research
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# Soligenix, Inc. (SNGX-NASDAQ)

***SNGX: Planning for Second Phase 3 Study for HyBryte™ in CTCL…***

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SNGX is valued at $5.00 per share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (04/24/23) | $1.52 |
| **Valuation** | **$5.00** |

## OUTLOOK

On April 24, 2023, Soligenix, Inc. announced the submission of a Type A meeting request with the U.S. FDA to initiate discussions regarding the design of a second Phase 3 study of HyBryte™ for the treatment of cutaneous T cell lymphoma (CTCL). We anticipate the meeting occurring approximately 30 days following the FDA's receipt of the meeting request, and for the meeting minutes to be available approximately 30 days after the meeting occurs. The fact that the FDA has categorized this meeting as Type A (the highest priority) is very encouraging and demonstrates the agency's responsiveness and continued collaboration in the development of HyBryte for CTCL. We expect the details of the study to be announced following receipt of the meeting minutes.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$14.06** |
| **52-Week Low** | **$1.46** |
| **One-Year Return (%)** | **-83.50** |
| **Beta** | **1.76** |
| **Average Daily Volume (sh)** | **38,879** |
| **Shares Outstanding (mil)** | **3** |
| **Market Capitalization ($mil)** | **$4** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **7** |
| **Insider Ownership (%)** | **4** |
| **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 2018 Estimate** | **-0.3** |
| **P/E using 2019 Estimate** | **-0.3** |

| | |
|---|---|
| **Risk Level** | **High** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2022 | 0.2 A | 0.2 A | 0.2 A | 0.4 A | 0.9 A |
| 2023 | 0.2 E | 0.2 E | 0.2 E | 0.2 E | 0.8 E |
| 2024 | | | | | 6.0 E |
| 2025 | | | | | 17.0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2022 | -$1.52 A | -$0.83 A | -$1.15 A | -$1.28 A | -$4.81 A |
| 2023 | -$1.25 E | -$1.30 E | -$1.45 E | -$1.54 E | -$5.55 E |
| 2024 | | | | | -$3.06 E |
| 2025 | | | | | -$2.38 E |

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## WHAT'S NEW

### Business Update

*Planning for Second Phase 3 Trial of HyBryte™ in CTCL*

On April 24, 2023, Soligenix, Inc. (SNGX) announced the submission of a Type A meeting request with the U.S. FDA to discuss the design of a second Phase 3 study of HyBryte™ (SGX301, synthetic hypericin) in the treatment of early stage cutaneous T cell lymphoma (CTCL). This follows the company's Type A meeting with the FDA earlier this month to discuss the refusal to file (RTF) letter previously issued in regards to the company's new drug application (NDA) for HyBryte for the treatment of early stage CTCL. At that meeting, the FDA stated it is going to require positive results from a second clinical trial in addition to the positive results from the Phase 3 FLASH study in order to accept an NDA filing. The second Type A meeting will involve discussion of the company's proposed clinical protocol. By conducting a second Type A meeting with Soligenix, the FDA is showing it is extremely responsive and willing to work with the company to advance the CTCL program at an expedited pace, which is a very encouraging sign.

The RTF was definitely a big disappointment and an unexpected development, however after speaking with management it is clear the company is committed to getting HyBryte approved in CTCL as quickly as possible. Investors should keep in mind that the second Phase 3 study in CTCL is unlikely to take as long to conduct as the first one, as the company is now much more familiar with the CTCL landscape, the KOL's, and patient advocacy groups. In addition, the fact that positive results were obtained in the first Phase 3 study means that it will likely be easier to enroll patients, which should help to reduce timelines.

The company has filed an S-1 as we believe a financing will need to occur to help fund the second Phase 3 study in CTCL. Soligenix did receive grants to help cover the cost of the FLASH study and we anticipate that grant applications will be submitted to help cover the cost of the second Phase 3 study, however there is no guarantee that funding will be secured.

Lastly, Soligenix is still pursuing discussions with the EMA and the MHRA regarding the potential for HyBryte to be approved in the E.U. and U.K., respectively, based on the results of the FLASH study. We anticipate the company providing an update on those regulatory pathways later this year.

### Conclusion

We were very discouraged to hear that the FDA is going to require positive results from a second Phase 3 study in order to accept the NDA for HyBryte in the treatment of CTCL. However, it is encouraging that the FDA has granted a second Type A meeting for the company to discuss its clinical trial protocol. Once an agreement is reached on the design of the second Phase 3 study we anticipate that it could be initiated relatively quickly. We also do not believe that it will take as long to conduct as the FLASH study given the company's greater familiarity with the CTCL landscape. We have made a number of changes to our model, including pushing out approval for HyBryte to 2027 and accounting for an additional financing that will need to occur in order to fund the second Phase 3 study. Our valuation now stands at $5.00 per share.

## PROJECTED FINANCIALS

| Soligenix, Inc. | 2022 A | Q1 E | Q2 E | Q3 E | Q4 E | 2023 E | 2024 E | 2025 E |
|---|---|---|---|---|---|---|---|---|
| License Revenue | $0.3 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Grant/Contract Revenue | $0.7 | $0.2 | $0.2 | $0.2 | $0.2 | $0.8 | $1.0 | $1.0 |
| SGX301 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $5.0 | $16.0 |
| Public Health Solutions | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| **Total Revenues** | **$0.9** | **$0.2** | **$0.2** | **$0.2** | **$0.2** | **$0.8** | **$6.0** | **$17.0** |
| Cost of Revenue | $0.6 | $0.1 | $0.1 | $0.1 | $0.1 | $0.4 | $1.8 | $4.8 |
| **Gross Income** | **$0.4** | **$0.1** | **$0.1** | **$0.1** | **$0.1** | **$0.4** | **$4.2** | **$12.2** |
| *Gross Margin* | *42.0%* | *53.9%* | *45.0%* | *40.0%* | *40.0%* | *44.7%* | *70.0%* | *71.8%* |
| Research & Development | $7.9 | $1.9 | $2.0 | $2.2 | $2.5 | $8.6 | $9.0 | $10.0 |
| General & Administrative | $6.7 | $1.7 | $1.8 | $2.0 | $2.1 | $7.6 | $10.0 | $16.0 |
| Other Expenses | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($14.2) | ($3.5) | ($3.8) | ($4.1) | ($4.5) | ($15.9) | ($14.8) | ($13.8) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Other Income (Net) | $0.7 | $0.1 | $0.1 | $0.2 | $0.1 | $0.6 | $0.5 | $0.5 |
| **Pre-Tax Income** | **($15.0)** | **($3.6)** | **($3.9)** | **($4.3)** | **($4.6)** | **($16.5)** | **($15.3)** | **($14.3)** |
| Net Taxes (benefit) | $1.2 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *7.7%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **Reported Net Income** | **($13.8)** | **($3.6)** | **($3.9)** | **($4.3)** | **($4.6)** | **($16.5)** | **($15.3)** | **($14.3)** |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($4.81)** | **($1.25)** | **($1.30)** | **($1.45)** | **($1.54)** | **($5.55)** | **($3.06)** | **($2.38)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 2.9 | 2.9 | 3.0 | 3.0 | 3.0 | 3.0 | 5.0 | 6.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

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## HISTORICAL STOCK PRICE




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