

Biotechnology

SNGX - OTC BB

May 12, 2016

Intraday Price 05/12/2016

\$0.77

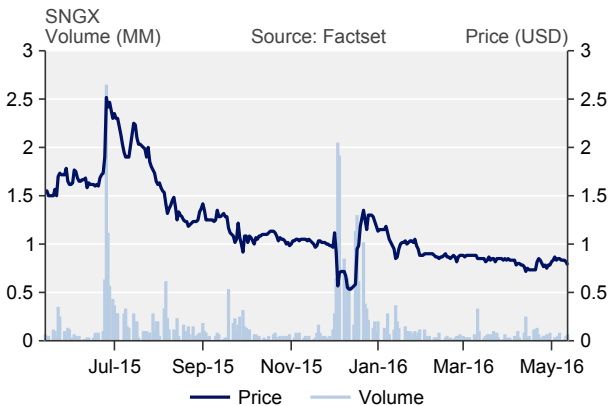
| | |
|--------------------------|-----------------|
| Rating: | Buy |
| 12-Month Target Price: | \$3.00 |
| 52-Week Range: | \$0.44 - \$2.95 |
| Market Cap (M): | 24 |
| Shares O/S (M): | 31.4 |
| Float: | 75.7% |
| Avg. Daily Volume (000): | 55 |
| Dividend: | \$0.00 |
| Dividend Yield: | 0.00% |
| Risk Profile: | Speculative |
| Fiscal Year End: | December |

Total Revenues ('000)

| | 2015A | 2016E | 2017E |
|-----------|--------------|--------------|--------------|
| 1Q | 289 | 2,631A | 1,746 |
| 2Q | 283 | 648 | 1,746 |
| 3Q | 829 | 648 | 1,746 |
| 4Q | 485 | 648 | 1,746 |
| FY | 1,886 | 1,944 | 6,985 |
| Prior | — | 2,594 | — |

Total Expenses ('000)

| | 2015A | 2016E | 2017E |
|-----------|--------------|---------------|--------------|
| 1Q | 1,847 | 4,537A | 2,381 |
| 2Q | 2,318 | 2,304 | 2,381 |
| 3Q | 2,099 | 2,304 | 2,381 |
| 4Q | 2,733 | 2,304 | 2,381 |
| FY | 8,996 | 11,409 | 9,525 |
| Prior | — | 9,176 | — |



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Soligenix Inc

Buy

Quarter Updates - Steady Progress

Summary

- Soligenix reported 1Q16 results with total revenues of \$2.6M, including contract revenues from BARDA (Biomedical Advanced Research and Development Authority) and NIAID (National Institute of Allergy and Infectious Diseases) for development of OrbeShield and ThermoVax combined with RiVax. Net loss for the quarter was \$1.1M or \$(0.04) per share and SNGX ended the period with \$4.3M in cash.
- The company released positive data from the Phase II oral mucositis study with SGX942 this past quarter. SGX942's novel mechanism of action as an Innate Defense Regulator showed the potential to address all stages of oral mucositis disease progression. The company is currently in talks with the US and EU regulatory authorities and expects to initiate a pivotal Phase IIb/III study before the year end.
- In addition, Soligenix continues to enroll patients for the pivotal Phase III study in cutaneous T-cell lymphoma with SGX301 (synthetic hypericin). Enrollment is expected to complete in 2H16.
- Non-dilutive government funding:
 - On March 17, 2016, NIAID had exercised a contract option of \$660,000 to accelerate regulatory interactions with the US FDA for its heat stable ricin toxin vaccine, RiVax, which further advanced the development of ThermoVax combined with RiVax as a medical countermeasure to prevent the effects of ricin exposure.
 - On May 5, 2016, the NIAID exercised a contract option for \$4.3 million to advance the thermostabilization technology for a RiVax vaccine. As of today, the company has been awarded a total of \$13.5M funding (with potential up to \$25M).

Details

Our Focus: SGX942 (Oral Mucositis): SGX942 is a peptide-based therapy for oral mucositis. The peptide alters the anti-infective and anti-inflammatory effects of the innate immune system (the first line of defense against infection and damage to the body). Chemotherapy induces significant mucosal damage (mouth, gut, etc.) that leaves patients highly susceptible to inflammation and infection. The phase II POC study (N=111), which evaluated three doses of SGX942, showed a 50% reduction in severe oral mucositis (from 18 days to nine days, P=0.099) in the 1.5 mg/kg group. In addition, there was a 67% reduction (from 30 days to 10 days, P=0.04) in those patients receiving the most aggressive chemo-radiation therapy. The data also showed a trend toward an increased incidence in the complete response of tumors in patients (47% placebo vs. 63% SGX942), suggesting that influencing the innate immune response may be playing an important role in fighting these tumors. The company is also in the process of assessing the impact of SGX942 on infection rate and mortality. Soligenix plans to engage the FDA on the size and scope of a pivotal study.

The phase II study (N=111) evaluated three doses of SGX942 (1.5, 3.0, and 6.0 mg/kg) vs. placebo, and data showed that the median duration of severe oral mucositis was reduced by 50% in the 1.5 mg/kg group (P=0.099) and 67% in patients receiving the most aggressive chemo-radiation therapy (P=0.04). The P-values surpass the prospectively defined statistical threshold of P<0.1 in the study protocol.

Bottom Line. The positive preliminary results of the SGX942 phase II study sets the stage for Soligenix to pursue partnerships for the phase II/III study. We are excited for the potential of this molecule to really have an impact in an area that represents a truly unmet medical need.

| Soligenix Inc., Inc. Income Statement (\$000) | | | | | | | | | | | | | | | | |
|---|---------|----------|----------|---------|---------|---------|---------|---------|---------|---------|--------|--------|---------|---------|---------|---------|
| Soligenix Inc.: YE Dec. 31 | 2012A | 2013A | 2014A | 2015A | 1Q16A | 2Q16E | 3Q16E | 4Q16E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E |
| Revenue (\$000) | | | | | | | | | | | | | | | | |
| SGX942 (Mucositis) (WW) | | - | - | - | - | - | - | - | - | - | 19,203 | 38,790 | 54,413 | 63,751 | 73,269 | 82,972 |
| oral BDP | | - | - | - | - | 648 | 648 | 648 | 1,944 | 6,985 | 9,701 | 11,580 | 14,394 | 14,684 | 14,830 | |
| SGX-301 | | | | | | | | | | | | 37,901 | 45,936 | 54,128 | 62,479 | 70,991 |
| Total Product Sales | | | | | | 648 | 648 | 648 | 1,944 | 6,985 | 28,904 | 88,270 | 114,743 | 132,416 | 150,432 | 168,794 |
| % Chg | | | | | | | | | | | | | | | | |
| License Revenue | | 565 | 3,000 | 8,641 | | | | | | | | | | | | |
| Grant Revenue | 3,145 | 2,659 | 4,043 | 127 | | | | | | | | | | | | |
| Cost of Grant Revenue | (2,593) | (2,554) | (5,314) | (6,882) | | | | | | | | | | | | |
| % Sequential Growth | | | | | | | | | | | | | | | | |
| Total Revenues | 552 | 670 | 1,729 | 1,886 | 2,631 | 648 | 648 | 648 | 1,944 | 6,985 | 28,904 | 88,270 | 114,743 | 132,416 | 150,432 | 168,794 |
| Expenses | | | | | | | | | | | | | | | | |
| % Chg | | 0 | 2 | 0 | 8 | 1 | (0) | 0 | 0 | 3 | 3 | 2 | 0 | 0 | 0 | 0 |
| Cost of Goods Sold & Acquired in Process R&D | | | 4,000 | | 2,232 | - | - | - | 2,232 | - | 2,890 | 8,827 | 11,474 | 13,242 | 15,043 | 16,879 |
| COGS % Sales | | | | | | | | | | | 10% | 10% | 10% | 10% | 10% | 10% |
| Research and development | 2,609 | 5,071 | 5,087 | 5,400 | 1,428 | 1,428 | 1,428 | 1,428 | 5,508 | 5,783 | 6,072 | 6,194 | 6,318 | 6,444 | 6,573 | 6,704 |
| R&D % Rev's | - | | | | | | | | | | | | | | | |
| G&A | 2,633 | 2,765 | 3,404 | 3,597 | 876 | 876 | 876 | 876 | 3,669 | 3,742 | 5,000 | 5,100 | 5,202 | 5,306 | 5,412 | 5,520 |
| G&A | | | | | | | | | | | | | | | | |
| Stock-based compensation - R&D | | | | | | | | | | | | | | | | |
| Stock-based compensation - G&A | | | | | | | | | | | | | | | | |
| Non-GAAP, Adj | | | | | | | | | | | | | | | | |
| Total expenses | 5,242 | 7,836 | 12,491 | 8,996 | 4,537 | 2,304 | 2,304 | 2,304 | 11,409 | 9,525 | 13,963 | 20,121 | 22,994 | 24,992 | 27,028 | 29,104 |
| Oper. Inc. (Loss) | (4,691) | (7,157) | (10,761) | (7,110) | (1,906) | (1,656) | (1,656) | (1,656) | (9,465) | (2,540) | 14,941 | 68,149 | 91,749 | 107,425 | 123,403 | 139,690 |
| Oper Margin | NM | NM | NM | NM | NM | NM | NM | NM | NM | NM | 1 | 1 | 1 | 1 | 1 | 1 |
| Interest Income | 6 | 2 | 1 | | | | | | | | | | | | | |
| Interest expense | | | | (8) | (4) | | | | | | | | | | | |
| Other Income (expense) | | | | | | | | | | | | | | | | |
| Change in fair value of warrant liability | | (3,655) | 3,436 | (1,202) | 760 | | | | | | | | | | | |
| Pre-tax income | (4,684) | (10,819) | (7,324) | (8,320) | (1,149) | (1,656) | (1,656) | (1,656) | (9,465) | (2,540) | 14,942 | 68,150 | 91,750 | 107,425 | 123,404 | 139,690 |
| Pretax Margin | | NM | NM | NM | NM | NM | NM | NM | NM | NM | 1 | 1 | 1 | 1 | 1 | 1 |
| Income Tax (Benefit) | (521) | 750 | 617 | 489 | - | - | - | - | - | (127) | 1,494 | 10,223 | 18,350 | 26,857 | 37,022 | 47,496 |
| Tax Rate | - | (0) | -8% | -6% | 0% | 0% | 0% | 0% | 0% | 5% | 10% | 15% | 20% | 25% | 30% | 34% |
| GAAP Net Income (loss) | (4,163) | (10,069) | (6,707) | (7,831) | (1,149) | (1,656) | (1,656) | (1,656) | (6,119) | (2,413) | 13,449 | 57,929 | 73,402 | 80,571 | 86,385 | 92,197 |
| GAAP-EPS | (0.37) | (0.65) | (0.32) | (0.30) | (0.04) | (0.05) | (0.05) | (0.05) | (0.19) | (0.07) | 0.36 | 1.49 | 1.81 | 1.91 | 1.97 | 2.02 |
| Non GAAP EPS (dil) | (0.37) | (0.67) | (0.43) | (0.30) | (0.04) | (0.05) | (0.05) | (0.05) | (0.19) | (0.07) | 0.36 | 1.49 | 1.81 | 1.91 | 1.97 | 2.02 |
| Wgtd Avg Shrs (Bas) - '000s | 11,136 | 15,463 | 20,638 | 26,066 | 31,279 | 31,592 | 31,908 | 32,227 | 31,752 | 35,314 | 37,520 | 39,044 | 40,629 | 42,279 | 43,995 | 45,782 |
| Wgtd Avg Shrs (Dil) - '000s | 11,136 | 15,463 | 23,585 | 26,066 | 31,279 | 31,592 | 31,908 | 32,227 | 31,752 | 35,314 | 37,520 | 39,044 | 40,629 | 42,279 | 43,995 | 45,782 |

Source: Company reports and Maxim Group

DISCLOSURES

Soligenix Inc Rating History as of 05/11/2016

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution

As of: 05/11/16

| | | % of Coverage Universe with Rating | % of Rating for which Firm Provided Banking Services in the Last 12 months |
|-------------|---|---------------------------------------|--|
| Buy | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months. | 86% | 34% |
| Hold | Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly outperform nor underperform its relevant index over the next 12 months. | 13% | 26% |
| Sell | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months. | 1% | 0% |

**See valuation section for company specific relevant indices*

I, Jason Kolbert, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Soligenix Inc

Maxim Group expects to receive or intends to seek compensation for investment banking services from Soligenix Inc in the next 3 months.

SNGX: For Soligenix, we use the BTK (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

SNGX: We have modeled oral mucositis and pediatric Crohn's disease with a 70% risk rate on both programs. We do not include any value for the biodefense programs. To the overall result, we apply a discount rate of 30%. We assume dilution and triangulate FCF, discounted-EPS, and sum-of-the-parts models, averaged and equally weighted (2021 revenues), to derive our price target.

Price Target and Investment Risks

SNGX: Soligenix faces multiple risks, which include the clinical efficacy of the product; the management of the clinical trial process; the manufacturing of the product; the company's ability to raise capital; the competitive landscape for this product; the decisions of regulatory bodies, such as the European Union and FDA; and the reimbursement environment. Small, capitalized biotechnology companies possess unique risks and can be very volatile. Our ability to "predict" data based on small and limited patient numbers in early (phase I) trials is limited. As such, investors should expect these risks, which are typically commensurate with the reward potential.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. **Price Volatility:** Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. **Price Volatility:** The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST



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