Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

October 28, 2022
David Bautz, PhD
312-265-9471
dbautz@zacks.com

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

Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Invited to Submit BARDA Contract Proposal for Filovirus Vaccines…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™ and CiVax™, SNGX is valued at $4.00 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 (10/28/22)	$0.69
Valuation	**$4.00**

OUTLOOK

On October 27 2022, Soligenix, Inc. (SNGX) announced that the Biomedical Advanced Research and Development Authority (BARDA) Division of Chemical, Biological, Radiological and Nuclear (CBRN) Medical Countermeasures has invited the company to submit a full contract proposal for the development of single-vial, adjuvanted, heat stable subunit vaccines to prevent filovirus infection. The proposal would be for a multi-year, multi-million-dollar contract to develop SuVax™ and MarVax™ vaccine candidates. Both candidates demonstrated robust protection four weeks after vaccination against the respective viruses in non-human primates. If approved by the FDA, each vaccine candidate would be eligible for a Priority Review Voucher as a tropical disease preventative.

SUMMARY DATA

52-Week High	**$1.02**
52-Week Low	**$0.40**
One-Year Return (%)	**-30.24**
Beta	**1.56**
Average Daily Volume (sh)	**88,209**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$30**
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 (%)	**-36.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.3**
P/E using 2019 Estimate	**-1.4**

Risk Level	**Above Avg.**
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)
2021	0.1 A	0.2 A	0.2 A	0.3 A	0.8 A
2022	0.2 A	0.2 A	0.2 E	0.2 E	0.8 E
2023					6.0 E
2024					17.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.06 A	-$0.05 A	-$0.09 A	-$0.09 A	-$0.32 A
2022	-$0.10 A	-$0.06 A	-$0.08 E	-$0.08 E	-$0.34 E
2023					-$0.48 E
2023					-$0.39 E

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

BARDA Invites Contract Proposal for SuVax™ and MarVax™ Vaccine Candidates

On October 27, 2022, Soligenix, Inc. (SNGX) announced that the Biomedical Advanced Research and Development Authority (BARDA) Division of Chemical, Biological, Radiological and Nuclear (CBRN) Medical Countermeasures has invited the company to submit a full contract proposal for the development of single-vial, adjuvanted, heat stable subunit vaccines to prevent filovirus infection.

BARDA invited Soligenix to submit a full contract proposal following review of its white paper entitled, "SuVax™: A Safe and Thermostable Single-Vial Adjuvanted Subunit Vaccine with Rapid Onset Immunity to *Sudan ebolavirus*". That paper proposed development of SuVax through Phase 1 clinical studies as part of a 5 year, $25 million dollar program. BARDA has requested that the full proposal include the potential for MarVax, a separate potential vaccine candidate against *Marburg Marburgvirus*.

Soligenix previously reported 100% protection in non-human primate models following challenge with either *Sudan ebolavirus* or *Marburg Marburgvirus*. In addition to showing success against filoviruses, those studies also served as an excellent proof-of-concept for the company's overall vaccine platform, which is capable of producing thermostabilized vaccines that can be stored in excess of 100°F.

To get a better understanding of the BARDA contracting process and where the vaccine candidates stand in the development pathway, we asked the company a series of questions, with their responses noted below.

1. **Can you go over how the BARDA contracting process works?**

   BARDA's contracting process begins with issuing a broad agency announcement which describes the subjects they are interested in supporting. This can be found here. They recommend that potential programs first approach BARDA for a TechWatch meeting (which we have done), then submit a white paper (~10 pages describing the program) and then if they are interested they request a full proposal, outlining any specific aspects they are interested in. A full proposal is a much more detailed description of costs and planned activities, and contains multiple options.

2. **Why does an additional submission need to be done if BARDA is already interested in the vaccines?**

   This is a normal process of BARDA contracting, as outlined in all their BAAs.

3. **The press release today says the proposal will be for 5 years to cover Phase 1 development. Will it really take 5 years to get through Phase 1?**

   It may be possible to move faster. However, this is subject to the Government's timelines, structuring of option periods, and administrative procedures.

4. **Positive results have already been seen in NHPs. Do additional animal studies need to be performed?**

   Again, this is at the discretion of the government. In this case, BARDA is interested in using vaccines in a "rapid onset" model. That is, in the event of an outbreak they want to be able to administer a vaccine in one or maybe two closely spaced shots to protect those who have been close contacts of a confirmed case of disease. In contrast, we have been focusing on a vaccine to provide durable protection, that is the doses are spaced apart more widely and meant to be used before an outbreak. In our studies we have seen promising indications that we can accelerate the dosing regimen and achieve more rapid protection, but we haven't completed any challenge (efficacy) studies with this dosing regimen. This will require

additional animal studies. As well, this program may well follow the animal rule, in which case animal studies will be needed to correlate with human immunogenicity studies throughout the program.

5. How quickly can safety studies in humans be performed and how many studies will be necessary?

Phase 1 safety studies will require manufacturing cGMP material, conducting a toxicology study and then filing an IND. Timelines here depend on how many activities are undertaken in parallel. In the context of a BARDA contract, this depends on government requirements and the negotiation procedure with BARDA, should they elect to move forward with negotiations after they receive the full contract proposal.

Likely a single Phase 1 safety study will be required. Efficacy studies will ultimately depend on the regulatory path (animal rule potentially or if there is another outbreak such as the current one in Uganda, it may be possible to run a Phase 2/3 type assessment in that context).

6. These products will be developed under the FDA animal rule. Can you describe how that differs from traditional vaccine development?

In traditional drug development, you first demonstrate safety in (usually healthy) humans (Phase 1), then explore efficacy and further explore safety in humans (Phase 2) and then run pivotal studies to demonstrate clinically meaningful and statistically significant efficacy while monitoring safety in a larger human population (Phase 3).

The Animal Rule explicitly recognizes that some diseases either occur so rarely/unexpectedly in humans that planning to evaluate efficacy is not possible or that it is unethical to expose patients to the disease. This applies to ricin poisoning for example, but may also apply to ebola variants since you can't predict when outbreaks might occur. With the Animal Rule, you still conduct safety in healthy humans, and safety and immunogenicity (meaning generation of antibodies in response to vaccination) in humans (a type of Phase 2 study) but the actual efficacy studies (meaning protection from infection/poisoning) are conducted in well-controlled animal studies. In order to be confident that the animal results really reflect what might have happened in humans you need to show that the disease process in the animals is like the disease process in the humans, that the animal response to the treatment/vaccine (e.g., antibody response) is like the human response to the treatment/vaccine (sometimes called "correlates of immune protection" for vaccines) and that when these conditions are satisfied, the animals are protected.

7. What is the potential market size for SuVax and MarVax?

Clearly filovirus infection (where filovirus is the family name for viruses that cause these diseases) is not common in the U.S. Equally clearly, they have pandemic potential, as Dr. Fauci has mentioned. Thus, the market is really one of prevention/protection in the event of outbreaks. The current way vaccines are used in this space is primarily in the context of outbreak rapid response, as described above. In principal, the vaccines could also be used in a more durable protection mode. However current vaccines that depend on viral vectors (like the vaccine approved for use specifically with Zaire ebolavirus infection) require very cold storage, which has significant logistical hurdles. However, our vaccines are designed to be thermostable – that is, to be able to be shipped and used at ambient temperatures. This may mean that it can be used more broadly than currently envisioned, though obviously it is difficult to predict outcomes/needs at this time. The potential market at the end of the day may be a procurement contract for stockpiling, but we will have to see. In addition, we believe that both vaccine candidates would be eligible for a tropical disease Priority Review Voucher, which was awarded for the vaccine against Ebola Zaire.

8. Is the US government the only potential purchaser or could additional government agencies potentially procure these vaccines?

There is no restriction on who might purchase the vaccines. Certainly, other government agencies, including other governments, could purchase them, subject to appropriate regulatory approval in the intended jurisdictions.

9. Are there other candidate vaccines for *Sudan ebolavirus* and *Marburg Marburgvirus*?

There are other candidates in development; however, these are primarily based on viral vector platforms, like adenovirus. These vaccines can raise appropriate immune responses but also have some disadvantages as well, including the need for cold chain storage and distribution (often at temperature less than -60º Celsius) and the potential for immune responses to the viral vector interfering with immune responses to the antigen of interest preventing repeated use of the same viral vector. Viral vectored vaccines are not always appropriate for people who are immune compromised. In contrast, our vaccine candidates are protein subunit vaccines. That means, we produce only the protein we want the immune system to learn to recognize and administer it with an adjuvant. Subunit proteins are considered one of the gold standards when it comes to safety.

Conclusion

The potential for a BARDA contract to develop the filovirus vaccines is a great opportunity for the company as it would provide the necessary non-dilutive capital to move those candidates toward approval. In addition, the opportunity for two Priority Review Vouchers is significant, as those continue to be sold for approximately $100 million each. We look forward to updates on the status of the proposal and with no changes to our model our valuation remains at $4.00 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.8	$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	**$0.8**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$6.0**	**$17.0**
Cost of Revenue	$0.7	$0.1	$0.2	$0.2	$0.2	$0.6	$4.0	$10.0
Gross Income	**$0.1**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$2.0**	**$7.0**
Gross Margin	*11.6%*	*51.0%*	*15.5%*	*10.0%*	*10.0%*	*21.0%*	*33.3%*	*41.2%*
Research & Development	$8.4	$1.7	$2.0	$2.2	$2.5	$8.5	$9.0	$10.0
General & Administrative	$4.8	$2.6	$1.4	$1.0	$1.1	$6.0	$14.0	$16.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($13.1)**	**($4.2)**	**($3.4)**	**($3.2)**	**($3.6)**	**($14.4)**	**($21.0)**	**($19.0)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.3	$0.1	$0.1	$0.1	$0.1	$0.5	$0.5	$0.5
Pre-Tax Income	**($13.4)**	**($4.3)**	**($3.5)**	**($3.3)**	**($3.7)**	**($14.9)**	**($21.5)**	**($19.5)**
Net Taxes (benefit)	$0.9	$0.0	($1.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*6.4%*	*0.0%*	*32.6%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($12.6)**	**($4.3)**	**($2.4)**	**($3.3)**	**($3.7)**	**($14.9)**	**($21.5)**	**($19.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.10)**	**($0.06)**	**($0.08)**	**($0.08)**	**($0.34)**	**($0.48)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	39.6	42.9	43.0	43.7	44.0	43.4	45.0	50.0

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

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.