

# THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

## Soligenix, Inc. (NASDAQ:SNGX)



**CHRISTOPHER J. SCHABER, Ph.D.**, has over 27 years of experience in the pharmaceutical and biotechnology industry, and has been Soligenix, Inc.'s President, Chief Executive Officer and a Director since August 2006. He also serves on the board of directors for the Alliance for BioSecurity and BioNJ, and is a member of the corporate councils for both the National Organization for Rare Diseases and the American Society for Blood and Marrow Transplantation. Prior to joining the company, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc. From 1996 to 1998, he was a Co-Founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, he was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr.

Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, his M.S. in pharmaceuticals from Temple University School of Pharmacy and his Ph.D. in pharmaceutical sciences from the Union Graduate School.

### SECTOR — PHARMACEUTICALS

**TWST: We last spoke to you in 2015. Can you give us an update on your late-stage assets and their market potentials?**

**Dr. Schaber:** Absolutely. If you recall when we spoke last, we reviewed our two business segments, which were a biotherapeutics business segment that focuses on oncology and inflammation and a vaccine/biodefense business segment that focuses on vaccines and therapeutics for civilian and military use. Since that time, we have continued to advance that pipeline in both segments.

We have now advanced our biotherapeutics business segment whereby we now have three Phase III clinical assets. The first is cutaneous T-cell lymphoma with SGX301, our synthetic hypericin, and for that we are actively enrolling patients in a pivotal Phase III clinical study. We have received both orphan and fast track designations with the U.S. Food and Drug Administration — FDA. We currently expect results by the end of this year.

We have for oral mucositis in head and neck cancer a separate molecule known as SGX942, or dusquetide, that is progressing to a pivotal study. This program has also received fast track designation from the FDA. We are currently targeting it to begin in the middle of this year. If all goes according to plan, we will have the potential for results as soon as the second half of 2018. This is a program that, at the last time we spoke, we did not have the Phase II clinical outcomes. We obviously did have a positive Phase II study so that we could build upon it with the pivotal Phase III study.

The last of our Phase III clinical assets is our pediatric Crohn's disease program with SGX203 or oral beclomethasone dipropionate. This is a pivotal study that has been cleared through the FDA. Right now we anticipate initiating that study by the end of 2017, but this study will be contingent upon additional funding such as through partnership. Here we have also received both orphan and fast track designations from the FDA.

Currently our focus is the first two clinical programs, the cutaneous T-cell lymphoma or CTCL, and oral mucositis. These programs have very nice market potentials. The cutaneous T-cell lymphoma, which again is FDA orphan and fast tracked, has a global market potential of approximately \$250 million. The oral mucositis in head and neck cancer, fast tracked with the FDA, has a global market potential of \$500 million-plus, so it is a significant market. Then the pediatric Crohn's global potential is \$200 million.

Our vaccine/biodefense business segment complements these biotherapeutic programs. It is advancing with government funding. We are currently operating under a \$24.7 million contract with the U.S. National Institutes of Health — NIH — to advance our ricin toxin vaccine, known as RiVax. We have moved this forward nicely whereby we have now demonstrated in a pilot nonhuman primate study that our vaccine offers 100% protection when exposed to an aerosol of ricin toxin. You cannot get better than a 100% protection.

We have conducted two Phase I human studies in healthy volunteers that showed the safety of the vaccine. And as I noted, we are currently advancing this program in our vaccine/biodefense business segment with government funding that is very important to our organization.

**TWST: Can you talk about your ThermoVax platform technology?**

**Dr. Schaber:** ThermoVax is a vaccine heat-stabilization platform technology. We can take liquid vaccines of a certain construct and lyophilize, or freeze-dry them to a powder so that they can then be stored outside the refrigerator for extended periods of time. If you are familiar with vaccines, many, probably in excess of 90%, require some form of refrigeration. For us, when we put vaccines into this ThermoVax system that we have, it has allowed us to then remove them from the refrigerator and store them at high temperatures for extended periods of time.

***“As much as 50% of all vaccines globally are wasted due to excursions from required cold chain temperature ranges. So it is significant, and the Department of Health and Human Services has also reported vulnerabilities in pediatric vaccine programs due to undetected cold chain variation.”***

Our positive proof of concept was our own ricin toxin vaccine. As a liquid, it is extremely labile, degrading within hours. But put into the ThermoVax system, we now have data that shows that we can store our vaccine in excess of one year at over 100 degrees Fahrenheit. And, upon reconstitution with the commodity sterile water for injection, it maintains 100% of its activity, zero degradation.

These profound results have really allowed us to move forward with the NIH to get that large contract that I spoke of for our heat-stable ricin toxin vaccine, RiVax. With our ThermoVax technology, we have also been able to show positive data with anthrax, HPV and Ebola vaccines, for which we have collaborated with both Hawaii Biotech and the University of Hawaii using their Ebola antigen.

**TWST: Somewhere in your company literature you cite that the World Health Organization estimated that 50% of vaccines go to waste; is that correct?**

**Dr. Schaber:** Yes, as much as 50% of all vaccines globally are wasted due to excursions from required cold chain temperature ranges. So it is significant, and the Department of Health and Human Services has also reported vulnerabilities in pediatric vaccine programs due to undetected cold chain variation. This is a significant issue in terms of cold chain storage and distribution.

Those variations or deviations could ultimately impact the quality of the vaccine that you are trying to get to the end user. This is a technology that really would eliminate not only the cold chain cost, but would also allow for distribution, especially to those regions of the world where refrigeration is difficult to maintain, like in the developing world.

**TWST: Can you elaborate a little bit more on how you want to use ThermoVax? Obviously it is a platform for your own vaccines in development internally, but do you intend in some way to also partner with others or to license it out?**

**Dr. Schaber:** That is our intent. Obviously, first and foremost,

as you have clearly outlined, it is being used to advance our vaccines. It is always good to have your own vaccine that you can couple with the technology and move it forward in development. But this platform does have the potential to expand beyond biodefense to emerging infectious diseases. That is something that we are looking at, and we have had a number of business development discussions around just that.

It has some unique properties, and you could even use this technology on the biosimilars front, which has been receiving a great deal of focus over the last several years. Because really when you are dealing with a lyophilization process you are, at most, adding a small amount of generally recognized as safe or GRAS ingredients. You are not changing the structure of the ultimate vaccine at the end of the day. So there is the potential that ThermoVax could be used with biosimilars, whereby at the end of the day you could have a biosimilar vaccine that is differentiated from the branded vaccine by heat stabilization.

**TWST: You mentioned also in your company literature that you wanted to take advantage of a U.S. government biodefense Priority Review Voucher program. Can you elaborate on what that is, and what it would mean to the company?**

**Dr. Schaber:** As you may know, biodefense drug development programs do not typically receive funding from life science investors. They have been a little hesitant to invest in the biodefense sector, because, at the end of the day, companies developing biodefense medical countermeasures — MCMs — are not guaranteed government procurement contracts to stockpile their drug upon FDA approval. Further, the true market potential of such drugs is only defined when there is a catastrophic event. God forbid that would occur. Because of this, the burden of MCM development funding has fallen predominantly on the government, like the NIH and/or the Biomedical Advanced Research and Development Authority — BARDA.

Now, with the recent passage of the biodefense Priority Review Voucher — PRV — program, it has created the potential to not only entice drug companies to develop in the biodefense area to address this area of unmet need, but it also has the potential to entice investors to fund biodefense companies. The reason being, with this PRV program, which is similar to other PRV programs in pediatric rare diseases and tropical diseases, if you are successful in obtaining FDA approval for your drug, you have the potential to receive a PRV that could then be used in two distinct ways: accelerating FDA review of your next drug development program, whereby the PRV qualifies you for a FDA priority review time of approximately six months, or you can sell the PRV, which has been significant. These PRVs have sold for as much as \$300 million to larger pharmaceutical companies to accelerate the FDA review times for their development programs.

This biodefense PRV program now provides an opportunity to obtain funding by someone other than the government. A potential

investor can now say, I may not be able to quantify a biodefense market if FDA approval is achieved, i.e., whether or not the company is going to receive a government procurement contract, but I can put a potential dollar figure to this asset with the PRV program if it were to receive FDA approval.

**TWST: Now the last time we spoke, you talked about how there is really not much competition in the areas that you develop in. In fact, in many instances, there is almost a lack of care and real unmet need. Can you elaborate a little bit on that, as far as some of your late-stage assets in terms of how they are filling a gap?**

**Dr. Schaber:** If you look at our pipeline diagram, you see that essentially all of our programs are orphan and/or fast track designated. Orphan designation oftentimes applies to a rare disease population for which there is a need, and the fast track designation is specifically for areas of unmet medical need. So for cutaneous T-cell lymphoma, there is currently no approved frontline therapy for the treatment of early-stage cutaneous T-cell lymphoma. We hope SGX301 will be the first there.

With oral mucositis in head and neck cancer, there is no approved drug, so again, we hope that SGX942 will be the first there as well. In pediatric Crohn's disease, specifically for frontline mild to moderate disease, there is no approved therapy in the U.S. The only approved therapies are for moderate to severe disease with the biologics Remicade and Humira that have somewhat negative safety profiles associated with them over the long term. So we really have potential to fill unmet medical needs in some very unique and important patient populations for which there is no approved and/or adequate drug therapy, especially for first-line treatment.

***“Right now our cash position and other instruments like our government grants and contracts have a runway that really goes beyond 12 months to get us to some important inflection points with some of programs.”***

Also of important note, with our ricin toxin vaccine, RiVax, we have orphan status and are a world leader in ricin toxin vaccine development. Thus we are looking to be the first approved here as well. Our therapeutic OrbeShield, which is another product in our biodefense segment we did not speak about today, is orphan and fast tracked for gastrointestinal acute radiation syndrome due to the significant unmet medical need in this area of biodefense. Across our entire pipeline and our two business segments, we are focused on filling voids that currently exist.

**TWST: One aspect about your pipeline we haven't really gone over is something called SGX943 for melioidosis. Can you elaborate on that as well as perhaps talk a little bit more about the vaccines in the areas of anthrax or Ebola?**

**Dr. Schaber:** For us, the SGX943 is really an extension of the active ingredient that we are using in our oral mucositis in head and neck cancer program. This molecule, SGX94 or dusquetide, has a very unique mechanism of action in which it not only reduces inflammation, but it also clears infection and promotes tissue healing. As you would imagine, this mechanism has a nice role in oral mucositis, where you are trying to heal and reduce infection of the open sores, as well as reduce the inflammatory cascade causing these ulcers, which are unbearably painful.

As you would imagine, SGX943 or dusquetide, with its unique mechanism of action, also has the potential to treat emerging and antibiotic-resistant infectious bacterial diseases, like melioidosis, which is a biodefense application. We are really trying to utilize our proprietary technology, not only for clinical indications, but on the biodefense front wherever possible.

To the point you were making on the other vaccines, the anthrax and Ebola, we currently do not have our own vaccines there. As previously noted, we are collaborating with the University of Hawaii and Hawaii Biotech to stabilize their Ebola subunit antigen with our ThermoVax. Thus far we have been able to demonstrate some positive initial proof of concept in stabilizing Ebola. This work will continue with additional government funding, which we are pursuing with our collaborators. Hopefully we continue to have some success there.

**TWST: Can you give us a status update on what you believe to be your key agreements? And can you mention if you are seeking any new agreements right now, and if so, what type and for what purposes?**

**Dr. Schaber:** When you say agreements, I assume you are speaking to business development. As you know I must be very careful here, because nothing is done until it is signed and can be disclosed publicly.

What I can disclose is, in addition to Hawaii Biotech and the University of Hawaii for the Ebola, we do have collaborations around our ricin toxin vaccine with Emergent BioSolutions and IDT Biologika. They are assisting us with its manufacture. Most notably and recently, just as of last September of 2016, we signed an important partnership

agreement with SciClone Pharmaceuticals, giving them the rights to our SGX942 in oral mucositis for the greater China market, where they have significant expertise.

As you would imagine with late-stage assets, we are in a number of discussions and remain active on this front to identify potential partners. Ultimately, we will see where things go. Hopefully next time we talk I will be in the potential position to discuss additional partnerships.

**TWST: What is your funding status? Are you now seeking anything in that area?**

**Dr. Schaber:** We did a small raise in December of 2016 to fund some of our late-stage programs and to assist us with up-listing the company from the Bulletin Board to the Nasdaq market. Right now our cash position and other instruments like our government grants and contracts have a runway that really goes beyond 12 months to get us to some important inflection points with some of programs like CTCL, and so there is not an immediate need for capital at this point.

But you are always interacting with investors and making sure people know your story and that we are now a Nasdaq-listed company, a very important milestone for us. We are trying to get our story out even more so because the investor universe is much larger for us now than when we were a Bulletin Board company. We will continue to do

that work, but don't anticipate needing any capital raise through equity financings in the immediate near term.

**TWST: What do you perceive to be your chief challenges right now?**

**Dr. Schaber:** Our chief challenges are always making sure that the company and the programs are funded, first and foremost. It is really to have a laser focus on the clinical programs. As you know, drug development has more failures than successes, but we believe we have been able to move our technology forward and have had a level of success.

Ultimately though, success is measured by getting it over the finish line and FDA approved. For us, with our cutaneous T-cell lymphoma, which is the lead program and nearest-term event, it is to make sure that we are conducting a quality study and not leaving any stone unturned with regard to execution so that we give ourselves the highest probability of success, and that is what I and my team here are predominantly focused on.

**TWST: Some of the common links in your pipeline are biodefense application, cancer, as well as just orphan and fast track designation. Can you talk about any longer-term vision for the company and whether you see yourselves staying with those themes, or do you want to expand them, and if so, how?**

**Dr. Schaber:** Currently the expertise of our team, which is many years, lies predominantly in drug development, specifically with orphan/rare diseases and unique development programs. We anticipate maintaining this theme moving forward in our core therapeutic areas of expertise: oncology, inflammation and infectious disease. However, in the near term we must continue to remain focused on the task at hand, that is, making sure that we give ourselves every opportunity for potential success in bringing the current assets across the finish line. While doing this, we must also remain opportunistic with regard to business development in securing potential partnerships for these assets that make sense for Soligenix and its shareholders.

However, it's also important to note that some of our current assets are tailor-made for a small company like Soligenix to commercialize on our own. In the area of biodefense, where you have one customer being the government, it is relatively straightforward assuming we are fortunate enough to get FDA approval. On the therapeutics side, in areas like cutaneous T-cell lymphoma, you don't need a large commercial unit to launch SGX301 effectively in the United States. The Soligenix management team and board, we are looking at this very carefully as a potential opportunity to transition from development to commercialization as a way to continue to build shareholder value.

**TWST: What do you want a potential investor in Soligenix to know today?**

**Dr. Schaber:** Given the assets we have and their stages of development, we believe that folks should really focus on the company and its pipeline. We have a number of relatively near-term events like the cutaneous T-cell lymphoma, where you have the potential for Phase III readouts as soon as the end of 2017. With oral mucositis in head and neck

cancer, Phase III data is currently expected by the end of 2018, and with pediatric Crohn's disease there is the potential for data as soon as the end of 2019, assuming additional support.

We have multiple shots on goal to mitigate risk and are not necessarily relying solely on one particular program for the company. Given where our market cap is today, Soligenix should be appealing to those looking to maybe take a little bit more risk investing in biotech, but ultimately the payout, if we are successful even in one of our programs, is going to be a significant return on investment.

**TWST: Is there anything else you want to mention that we haven't covered?**

**Dr. Schaber:** I think you really hit it all. We have hit the fact that we have multiple products all with fast track and/or orphan drug designations with significant market potential and a potential nice return on investment. We have three Phase III assets on the therapeutic side, again with the potential for cutaneous T-cell lymphoma at the end of 2017, oral mucositis at the end of 2018 and pediatric Crohn's end of 2019. The pipeline provides for a nice news-flow stream over the next 12 to 24 months, which is always important in building that value and getting the story out there.

We have good collaborations established, like the one with SciClone Pharmaceuticals for the greater China market with SGX942, and we are looking to build upon that. We will continue to aggressively pursue other potential partnerships. Then we have the biodefense business segment that helps cover some of our operating expenses through government funding. We believe we have very good technology there that we can advance. And, if we are successful in achieving an FDA approval, we are not only positioned for potential procurement contract with the government, but for priority review voucher that you as we discussed a little earlier in the interview.

We have covered all of the key topics. The only thing I would add is I believe we have a strong management team and board of directors at Soligenix, and I would urge everyone to take a close look at our corporate website. We have a lot of good information on it from publications to audio presentations to webcasts that could really help educate the reader much more on what we are doing and what data we have generated to date.

**TWST: Thank you. (KJL)**

**CHRISTOPHER J. SCHABER, PH.D.**

**President and CEO**

**Soligenix, Inc.**

**29 Emmons Drive**

**Suite C-10**

**Princeton, NJ 08540**

**(609) 538-8200**

**(609) 452-6467 — FAX**

**www.soligenix.com**