THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

Soligenix, Inc. (OTCBB:SNGX)

CHRISTOPHER J. SCHABER, PH.D., is President and Chief Executive Officer of Soligenix, Inc. He has over 25 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been President and Chief Executive Officer and a director of Soligenix (OTCBB:SNGX) since August 2006. He was appointed Chairman of the board on October 8, 2009. He also serves on the board of directors of the Biotechnology Council of New Jersey — BioNJ — since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate councils of both the National Organization for Rare Diseases — NORD — and the American Society for Blood and Marrow Transplantation — ASBMT — since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, preclinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a Co-Founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber 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. degree from Western Maryland College, his M.S. degree in pharmaceutics from Temple University School of Pharmacy and his Ph.D. degree in pharmaceutical sciences from the Union Graduate School.

SECTOR — PHARMACEUTICALS

TWST: Can you describe your company and its purpose?

Dr. Schaber: Our company's tagline concisely describes its purpose, and that is: rising to the challenges of rare disease treatment. Our mission is to address unmet medical needs by targeting rare disease indications in inflammation, oncology and biodefense.

TWST: Which of the company's programs is furthest along, and when might be the earliest the drug candidates could be commercialized?

Dr. Schaber: We will be initiating our pivotal Phase III clinical trial for SGX301, our synthetic hypericin, in the treatment of cutaneous T-cell lymphoma, or CTCL, in the second half of this year, with results expected in the second half of 2016. SGX301 has both orphan and fast-track designations with the FDA, as well as recently receiving orphan designation from the European Commission.

In addition, we have a pivotal Phase III clinical trial for SGX203, our oral beclomethasone dipropionate, or BDP, in the treatment of pediatric Crohn's disease. Here we have both orphan and fast-track designations as well. We anticipate beginning this study by year-end, depending on funding, with results expected in the second half of 2017. Both of these pivotal Phase III clinical studies that are set to begin in 2015 are supported by an already compelling clinical data and will be the studies used to support marketing registration with the FDA.

Of important note, we've also recently completed enrollment in our Phase II proof-of-concept clinical trial with SGX942, which is our novel, innate defense regulator technology, in the treatment of oral mucositis for patients receiving chemotherapy and radiation therapy for head and neck cancer. These results are expected by the end of the year. If you look at these late-stage programs, the earliest to reach commercialization would most likely be our CTCL indication candidate, for which we would anticipate potential approval as early as late 2017 or 2018.

TWST: Can you talk about what the market potential for this and other programs are in terms of estimated revenue or else the number of patients impacted?

Dr. Schaber: Sure. Both our product candidates in Phase III development that I just outlined have significant worldwide market potential of over $200 million. We estimate that there are as many as 20,000 CTCL patients in the U.S. and a comparable number in Europe. This is for SGX301.

For SGX203, there are as many as 80,000 pediatric Crohn's patients. The estimated market potential for SGX942 in oral mucositis in head and neck cancer is over $500 million, with as many as 90,000 patients in the U.S. and a comparable number in Europe. Although rare disease markets are thought of as small, the markets for diseases for which there remains or exists an unmet medical need have substantial potential provided the clinical results are positive and compelling.

the government — currently up to $57 million — has allowed us to develop multiple programs and build a very robust pipeline given our size and market cap.

Just to add, our vaccine/biodefense business segment is being developed for national defense, which we take great pride in. This segment includes our heat-stable ricin toxin vaccine known as RiVax, for which we have a NIAID contract award of up to $24.7 million. This compound has demonstrated 100% protection against aerosolized ricin toxin in vaccinated animals exposed to the toxin.

Then, we have our OrbeShield biodefense therapeutic for gastrointestinal acute radiation syndrome that has both BARDA and NIAID contract awards that combined total up to approximately $32 million. Here, we've also demonstrated positive survival in animals exposed to lethal doses of radiation. Both are very important programs in the biodefense sector.

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TWST: The $500 million for the oral mucositis compound: Is that a worldwide figure, or is that for just the U.S. and Europe?

Dr. Schaber: That's a worldwide figure.

TWST: Can you talk about or address the health of your company's financials and whether you have adequate funding for all your development programs? And as part of that response, could you describe your recent equity purchase agreements?

Dr. Schaber: Of course. We do have adequate funding to conduct our Phase III program in cutaneous T-cell lymphoma. We will be exploring additional funding opportunities for our pediatric Crohn's disease trial in the form of government grants. You may have seen, if you visited our website, that we are very active in the pursuit of nondilutive funding through government grants and contracts. There's also the potential for funding through partnership, which we are also looking at as well for potential financing.

Our recent $10 million equity purchase agreement that you alluded to has the potential to provide the company with another funding option; however, please keep in mind that the use of this equity instrument is at our sole discretion, which is important as we pursue other activities of nondilutive funding through government grants and potential partnering. We have a number of potential avenues that we can travel to support the company, which includes government grants and contracts, as we currently have up to $57 million in contract funding for the vaccine/biodefense segment of our business.

TWST: You mentioned the government funding. Which are the agencies that are providing this funding, and what sort of reciprocity arrangement does the acceptance of these funds commit you to as a company?

Dr. Schaber: Obviously, the grant or contract, depending on what it is, then dictates how these funds will be used to support development. We currently enjoy collaborative arrangements with various government agencies, like the NIAID and BARDA, and work with these groups very closely. As you would imagine, the significant funding we have been fortunate enough to receive from

TWST: Which of these programs is considered to be the most important for defense, and why?

Dr. Schaber: Both of them for different reasons. Obviously, on the vaccine side, there is no vaccine for ricin toxin exposure. We are the world leader in ricin toxin vaccine development. This has garnered considerable support, and as you may have read or may know, ricin toxin itself is extremely easy to make. It is a byproduct of the castor bean. Over the last several years, there have been bio threats of ricin toxin exposure. Fortunately, these events have been managed without casualties. It is very important to get a vaccine in this area.

Regarding the acute radiation syndrome, this is of high interest to the government. The government has spent over $600 million for radiation-injury types of vaccines and therapeutics. We are focused on the gastrointestinal subsyndrome of acute radiation syndrome in which we have generated some very positive data with a novel oral delivery of the therapeutic that we call OrbeShield, containing the active ingredient beclomethasone dipropionate. This is also a very important area. We believe we are well along in development with regard to the gastrointestinal subsyndrome.

TWST: When is the earliest that these would be used in defense applications?

Dr. Schaber: When talking about FDA approval, we still have several years to go. However, with biodefense, what's important to note is that, if there is a bioterrorist event that takes place, the government can procure these drugs under what's known as Emergency Use Authorization. We have to be ready and poised that in the event that does occur, then we are prepared to supply it. Luckily for us, for our ricin toxin vaccine and our OrbeShield for gastrointestinal acute radiation syndrome, we not only can manufacture large quantities of material, but we also have generated some very positive preclinical efficacy data in animals and have shown considerable safety in humans as well that have been treated with our drugs. We are positioned nicely if we are called upon to provide these vaccines and therapeutics.

TWST: You have a platform called ThermoVax that is a heat-stabilization technology. Can you talk about what it is and why is it so significant for vaccine technology, and further, if you intend to license it out to other companies?

Dr. Schaber: In our presentation, we typically will talk about the market opportunity as it relates to certain information that has come out in the public domain. One is the World Health Organization's report that noted that about half of all vaccine doses globally are lost due to temperature excursions. The U.S. Department of Health and Human Services reported similar findings with pediatric vaccines. So there is definitely an unmet medical need here that we believe ThermoVax, our vaccine heat-stabilization platform technology, has the potential to satisfy.

The primary proof-of-concept work with the ThermoVax technology has been with the proprietary vaccine RiVax, meaning the ricin toxin vaccine. We also apply this to our anthrax vaccine known as VeloThrax. In addition, we have announced publication of data that was generated through the University of Colorado that demonstrated heat stability of a human papillomavirus — HPV — vaccine.

ThermoVax is a proprietary drying process that allows us to freeze-dry, or lyophilize, liquid vaccines of a certain construct. It really has the potential to be game-changing as we move forward. We will continue to generate data to increase this body of knowledge. We are also very active in business development here, and are speaking with a number of groups from vaccine companies to not-for-profits to the government and hope to have feasibility partnerships in place throughout the coming years.

As you may have read, we already have an important feasibility collaboration in place for an Ebola vaccine on which we are working with the University of Hawaii and Hawaii Biotech to demonstrate that we can stabilize their Ebola subunit vaccine. That work has just started. We expect data in the first half of 2016, but this will continue to allow us to build on that body of knowledge and hopefully garner additional interest from others to work with us. We are actively looking to do feasibility and ultimately to out-license this technology or partner this technology.

TWST: Who is your competition in all of the areas you are in?

Dr. Schaber: The nice thing is, when you are working in areas of unmet medical need, there often is little competition. To that end, there are a number of companies that are working on developing either vaccines or therapeutics in biodefense and infectious disease. However, as I noted regarding our ricin toxin vaccine, we are the world leader in development. We are very far along. I don't see significant competition as we look at it today, especially when it's coupled with our heat-stabilization technology, ThermoVax. We are quite advanced as I noted in our gastrointestinal acute radiation syndrome therapeutic, OrbeShield.

There is an unmet medical need that exists for first-line treatment in cutaneous T-cell lymphoma. Currently, the only drug that is used for early-stage disease is the drug PUVA, which is not FDA-approved in CTCL and thus used off-label. Again, it's not approved for the disease itself. PUVA is made up of the drug psoralen plus UVA light.

Unfortunately, psoralen is a known mutagenic chemical, and UVA light is a carcinogenic light source, the equivalent of sunlight. This particular product carries a black-box warning for increased risk of malignancies, so it is not ideal to treat cancer in the chronic setting. We believe our SGX301, synthetic hypericin, provides a much safer alternative, and a very positive option for clinicians and patients in this disease.

Then, in pediatric Crohn's disease, the only approved drugs are the biologics, Remicade and Humira, which also carry black-box warnings on their labels for increased risk of malignancy and infection. Again, these are not ideal as first-line or front-line treatments in pediatric Crohn's patients. Currently what are used as first-line treatments are systemic steroids like prednisone. It is used off-label and is not approved for the disease.

So we believe our SGX203, oral beclomethasone dipropionate, really serves an important function because it is a locally acting topical steroid that does not have the same systemic exposure seen with prednisone. We provide an alternative or an option to systemic steroids with our very novel oral delivery of immediate and delayed release SGX203.

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TWST: Can you expand more on how your technology for cutaneous T-cell lymphoma is different from other technology for that same indication?

Dr. Schaber: Our SGX301 is synthetic hypericin, chemically synthesized using a patent-protected process. It is a safe drug that is applied to the lesions on the skin of cutaneous T-cell lymphoma patients followed by exposure to fluorescent light. After a short course of treatment, we see clearing of these lesions. That is very important, as it's a chronic disease. These patients can live for decades with the disease, so the safety and efficacy of therapy are very important. That's one thing that is not there currently.

The current treatment, PUVA, is made up of psoralen, a mutagenic chemical, along with UVA light, the equivalent of sunlight. That's why it carries a black-box warning for increased risk of cancers. Currently, PUVA is used off-label since it isn't approved in CTCL but is approved in other chronic diseases like psoriasis, which — by the way — doesn't seem to make it an ideal treatment for disease either. Clinicians really need to track the number of times they use PUVA in treating these reoccurring lesions that develop, because obviously, they want to make sure that they are not increasing the patients' risk for other types of cancers. That is not a concern with SGX301 our synthetic hypericin, which gives the clinician a lot of flexibility in

treating the cutaneous T-cell lymphoma earlier, more often and even for many years without having to keep count like they currently do with the more caustic therapy, PUVA.

TWST: Can you describe the main two agreements that you have going on, with an emphasis on what has been occurring in this last year?

Dr. Schaber: We do have a number of agreements in place. We have a development agreement with Emergent BioSolutions to implement a commercially viable, scalable production process for our ricin toxin vaccine, RiVax. We also have that collaboration I noted earlier with the University of Hawaii and Hawaii Biotech to develop a heat-stable Ebola vaccine, and a commercial agreement with SciClone Pharmaceuticals for our SGX942 in oral mucositis that is for the commercial rights in China.

In addition, we are also actively exploring a new biodefense and/or rare disease collaboration with Intrexon Corporation, headed by well-known life science entrepreneur R.J. Kirk, who is Soligenix's largest shareholder and is an enthusiastic supporter of the company. We are obviously also collaborating with the government under grants and contracts, and are looking to expand on these collaborations through filing and submission of additional grants and contracts with the government across our entire pipeline. In addition, we are pursuing opportunistic partnerships, especially ex-U.S. for our late-stage therapeutic programs and with our ThermoVax vaccine heat-stabilization platform technology.

TWST: Are there any, or can you describe any trends, laws or regulations that might be affecting the company at this time? And how might you be reacting to them?

Dr. Schaber: As it relates to us as a development phase company in both the therapeutic and biodefense sector, there is nothing specifically. We continue to drive our programs forward, working with the FDA and the government agencies like NIH and BARDA, and we really see no significant impediments other than having to execute on our programs and demonstrate that our products are effective at the end of the day.

TWST: What are your strategic objectives for the next year to two years?

Dr. Schaber: As you would imagine, it is to advance our late-stage clinical programs to trial completion. In the near term, it's our Phase II oral mucositis study in head and neck cancer with SGX942, for which we are anxiously awaiting data in the fourth quarter of this year; this is imminent. Given the Data Review Committee's recommendation with this trial to extend enrollment by an additional 20 patients and enroll these patients into a single dose of SGX942 only and placebo, we are cautiously optimistic about the outcome.

Then, we have our two Phase III pivotal studies in pediatric Crohn's and cutaneous T-cell lymphoma. We anticipate initiating both studies by year-end, with data throughout the next two years. We are looking at the second half of 2016 for topline results of our Phase III study in cutaneous T-cell lymphoma and the second half of 2017 with results for our pediatric Crohn's program. Those are critical. In addition, as you would imagine, from a strategic objectives perspective, it's not only about advancing these programs but also exploring partnership opportunities through our various programs. That is something we are very active in across our entire pipeline.

TWST: What do you view as your main challenges right now, and how are you seeking to address them?

Dr. Schaber: Our main challenges, similar to most other life science companies, are positioning our drug candidates as best we can to demonstrate they are safe and effective in the patient populations that need them the most. This is done through good science, good people, quality execution and adequate funding. We believe we are positioned well with the first three, but we must continue to secure ongoing funding to move our late-stage programs forward. We hope to continue to do this, in large part, with nondilutive funding from government grants and contracts as well as through potential partnerships and opportunistic financings.

TWST: Are there any operational management changes that you are looking to implement in the next year, and if so, can you describe them and what they are intended to achieve?

Dr. Schaber: Luckily, there are no major needs or gaps at this time. However, being a small biotech company that is rapidly evolving, as I am sure you are aware, we must always be on the lookout for high-quality, experienced individuals who can make our organization better and help to take it to the next level. That's something that we do on an ongoing basis as we advance our clinical pipeline.

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

Dr. Schaber: In summary, that we have a robust and diversified pipeline with late-stage assets that are designated as fast-tracked and with orphan status by the FDA. We have a vaccine/biodefense division with current funding in excess of $57 million to support those programs. In addition, that we have multiple near-term potential value drivers over the next 12 to 24 months that will potentially build significant value for investors. Just as important, we have an experienced and dedicated team at Soligenix that is committed to aggressively moving this important pipeline forward to potential success.

TWST: Is there anything else you wanted to add that we haven't covered yet?

Dr. Schaber: No. I think you hit upon all the main points. I'd just like to conclude our discussion by asking your readers to please take a moment to check out the Soligenix corporate website at www.soligenix.com where they will find interesting and useful information. Thank you for the time today and for the opportunity to let me speak about the important work we are doing in areas of unmet medical need at Soligenix. It is greatly appreciated.

TWST: Thank you. (KJL)

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