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With their Lead Product Lorexys Serving the Blockbuster Market of Female Sexual Dysfunction focusing on Hypoactive Sexual Desire Disorder (HSDD) and a 60/300 Clinical Study Design, S1 Pharmaceuticals, Inc. is Well Positioned for Clinical Trails and to Bring their Product to Market in Three Years

Healthcare
Pharmaceuticals
(Privately Held)

Nicolas G. Sitchon, M.A., M.B.A.
Chief Executive Officer

BIO:
Mr. Sitchon has been S1 Pharmaceuticals' Chief Executive Officer since its inception in 2008. Before S1, Mr. Sitchon was Global Research & Development Controller at Bayer HealthCare Consumer Care Division, a subsidiary of Bayer AG from 2006 to 2008. Prior to Bayer HealthCare, Mr. Sitchon held positions in Marketing, IT, Business Intelligence, and Business Planning in the Cardiovascular and Neuroscience Franchises of Novartis Pharmaceuticals. Mr. Sitchon was recruited to Novartis' Leadership Development Rotational Program (LDP) in 2004 after completing his MBA at the Boston University School of Management. Mr. Sitchon had previously been on an academic medicine track, which included research at the University of California, San Francisco Brain Tumor Research Center and the University of California, Irvine Medical Center, with abstracts published in the Journals of Neuroscience and Neuro-Oncology. Mr. Sitchon attended the Boston University School of Medicine from 1999 to 2001, receiving a M.A. in Medical Science before pursuing a career in business. He completed his undergraduate studies at the University of California, Berkeley.

Company Profile:
S1 is an early-stage biopharmaceutical company developing therapeutic solutions for disorders of Women's Sexual Health. The most common type of Female Sexual Dysfunction (FSD) is a loss of libido (lack of sexual interest) known as Hypoactive Sexual Desire Disorder (HSDD). S1 is developing its lead product, Lorexys, as an oral drug and will seek to demonstrate that Lorexys can be the first safe and effective treatment approved by the FDA for HSDD in women.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Sitchon, what is the overall vision at S1?
Mr. Sitchon: Our vision for S1 was to have a leaner, faster-moving biopharmaceutical company focused on one therapeutic area without the constraints of big pharma. In addition, we wanted to target a therapeutic area that affects a large population and one with no FDA-approved solution.

CEOCFO: What did you decide to target, and will you tell us about that arena in general?
Mr. Sitchon: We decided to target women's sexual dysfunction. That is, women's libido. The indication is Hypoactive Sexual Desire Disorder (HSDD), which is an indication affecting more than 26 million women. I have seen personally the very real distress it can cause in patients with the disorder and we feel that it has been overlooked by the medical and biopharma community for various reasons. We also wanted to go after it because there is a high investment upside and the timing is right.

CEOCFO: What have you developed to help take care of this problem?
Mr. Sitchon: Our lead product is called Lorexys. For a drug as safe as it is, it had surprisingly and disproportionately high efficacy relevant to HSDD in the small studies we have done, and we think that implies a synergistic effect between its components. It comes in an oral dose form. It had rapid speed of onset, which

means that when you take it you do not need to wait three or four weeks before it kicks in. We expect that you can simply take it and four hours later you will know it is working. It is also, by design, very safe. It is a combination of two drugs that have already been approved for other indications in the past. Therefore, there is a large positive safety database, which will support our submission for a 505(b)(2) regulatory pathway. It is also centrally acting, so its molecular targets are in the central nervous system and it is non-hormonal.

CEOCFO: How does Lorexys work?
Mr. Sitchon: Right now, the understanding of HSDD, as far as central control, involves a balance of neurotransmitters. What we understand of Lorexys and its mechanism of action is that it puts back into harmony the imbalanced neurotransmitters in the brain in those who are affected by the disorder.

CEOCFO: How does it do that?
Mr. Sitchon: The mechanisms of action act by reuptake inhibition of the neurotransmitters norepinephrine and dopamine; and through specific serotonin receptor targets. Putting those neurotransmitters back into balance is the key to restoring central control of libido

CEOCFO: Where are you in the development process?
Mr. Sitchon: We have filed our Investigational New Drug application, IND, with the FDA and we are currently in that review period. Our plans are to initiate our Phase I clinical protocols this summer.

CEOCFO: How does S1 work differently from big pharma and what are the advantages of being a small company addressing one specific target?
Mr. Sitchon: This is a relatively controversial topic in our industry at the moment with strong opinions on both sides. Do you invest more in large pharma R&D or do you decrease big pharma R&D budgets and promote the proliferation of a larger number of smaller biopharmas allowing them to take on the higher risk, effectively diversifying the approach to innovation like an overall biopharma industry innovation portfolio? Clearly we are in the latter camp. We believe that the way to foster innovation and get biopharma back into doing its duty for society in a much more efficient way is to allow the proliferation of focused smaller biopharmaceutical companies. These are companies that do not have the slow moving, scripted decision-making characteristics of large companies, and who can afford to make higher risk-reward choices without the interference of a far-removed executive body that might over emphasize canned metrics for go, no-go decisions. To quote Bernard Munos formerly of Eli Lilly, "You cannot script innovation"…."You cannot boil it down to a code of best-practices…" Having more companies like us frees up biopharma-at-large to innovate. In that greater context, we at S1 Pharma believe that if the goal is to develop medicines that work, it is best to focus on one therapeutic area, become intimately familiar with the science behind that therapeutic area, and align the whole business to that end. As an example, we can select our individual scientific advisory board members and clinical advisors for a more personal and invested team dynamic. We can select our business board members to be in line. Everything can be in alignment from science to clinic to commercialization. We can make choices, such as executing a riskier clinical protocol that would benefit a subgroup patient population in need, that might not otherwise make it past all of the hurdles in a larger company.

There seems to be an increased awareness of us; in recent months we have had prominent thought leaders approach us to join our board. It is a very exciting thing. - Nicolas G. Sitchon

CEOCFO: What is the competitive landscape; are many companies looking for remedies in the HSDD arena?
Mr. Sitchon: As far as we know, there have been a handful of attempts, but there are only two clinical development programs that are going after HSDD right now. We actually do not believe that we are direct competitors with them, because we are the only current developer of a therapy for HSDD with CNS molecular targets. In fact, we are positioned as an adjunct therapy to any hormonal therapies that might make it to market.

CEOCFO: S1 Pharmaceuticals made some recent additions to its advisory board; is it complete now and how does that round up the picture for you?
Mr. Sitchon: We are thrilled about our scientific advisory board. There seems to be an increased awareness of us; in recent months we have had prominent thought leaders approach us to join our board. It is a very exciting thing. From the beginning we have had Dr. Robert Taylor Segraves, who is a well known and well respected key opinion leader, thought leader, in the field. We have added Dr. Molly Katz, another prominent thought leader, and there will be a press release soon with a number of additions whom we are very excited about. Then that should do it for our Phase I plan, and perhaps as we move into Phase II and start going after our EMA development plans, we may add some more to represent the larger international academic community.

CEOCFO: Are you funded to move forward?
Mr. Sitchon: So far, we have been privately funded. We are currently seeking our first institutional round, that is, our Series A to support our $6.5 million clinical development program that we have for Phase I.

CEOCFO: Why should investors pay attention to S1 Pharmaceuticals today?
Mr. Sitchon: Aside from the strength of our pipeline and team, we think the timing is right. There has been a lot of work done in the medical community since the late 1990's, which has led to a greater recognition of the prevalence of FSD and HSDD, and need for a treatment of the disorder. In that time there has been a handful of development programs and with each attempt, an increased awareness with FDA, clinicians, and the patient community. We think that those groups

believe that a solution will eventually come and we believe they are waiting. In our interactions with the FDA so far, indications are that they would be ready to approve a first-time medical and much needed solution for the disorder.

CEOCFO: How does working with two known drugs make it a much easier process?

Mr. Sitchon: The 505(b)(2) regulatory path typically carries less risk since there is usually a large positive safety database out there from prior studies. This can also help in terms of cost. The 505(b)(2) regulatory path is one of the main pillars of our value proposition.

CEOCFO: Would you tell us more about the value proposition that S1 presents?

Mr. Sitchon: We have a lead product that addresses an unmet medical need with poor therapeutic options. There is a potential $2.5 billion global HSDD market. Our lead product Lorexys has excellent scarcity value: it serves a blockbuster market, has no baggage, three years to market, manageable development cost and risk, and a strong IP position. We also have a proven, what we call, a "60/300" clinical study design and methodology that allows for unprecedented cost and robustness in a clinical trial for a drug of Lorexys profile. In addition, we plan to run studies that benefit 3.5 million women with breast cancer-linked HSDD. Lorexys will also help 3 million post menopausal women with HSDD in the United States, and millions more globally.

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