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COMPANY INTERVIEW

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Fibrocell Science Inc. (NASDAQ:FCSC)

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DAVID PERNOCK serves as Fibrocell Science Inc.'s Chairman of the board and Chief Executive Officer. Previously, he held various positions at GlaxoSmithKline, or GSK, most notably serving as Senior Vice President of Pharmaceuticals, Vaccines, Biologics, Oncology, Acute Care and HIV Divisions. Prior to that, Mr. Pernock served as President of Reliant Pharmaceuticals when Reliant was acquired by GSK. He was President of SmithKline Beecham—Puerto Rico prior to the GSK merger. Furthermore, Mr. Pernock served as a director of Martek Biosciences Corporation and is currently a member of the board of directors for Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX). Mr. Pernock holds a B.S. in business administration from Arizona State University.

SECTOR — PHARMACEUTICALS

(AZQ615) TWST: Please provide a brief overview of Fibrocell.

Mr. Pernock: Our focus on the patient drives everything we do, and as a result, our path forward is clear: to develop game-changing cell and gene therapies for localized treatment of the underlying cause of debilitating diseases affecting the skin, connective tissue and joints. Our proprietary autologous fibroblast technology is the foundation of our personalized biologics platform for creating cell and gene therapies. We use fibroblast cells from a patient's own skin to create localized therapies — with and without genetic modification — that are compatible with the unique biology of each patient and have the potential to address the underlying cause of disease. Currently, all of our research and development operations and focus are on gaining regulatory approvals to commercialize our product candidates in the United States; however, we may seek to expand into foreign markets in the future.

TWST: Fibrocell has a proprietary technology platform that utilizes autologous fibroblast cells. Talk about the platform and its key advantages for developing cell and gene therapies.

Mr. Pernock: The foundation of our personalized biologics platform is our proprietary autologous fibroblast technology. Fibroblasts are the most common cell in skin and connective tissue, and are responsible for synthesizing extracellular matrix proteins, including collagen and other growth factors, that provide structure and support. Because fibroblasts naturally reside in the localized environment of the skin and connective tissue, they represent an ideal therapeutic agent for the treatment of diseases affecting the skin, connective tissue and joints. Utilizing our autologous fibroblast technology, we use a patient's own fibroblast cells to create therapies that are compatible with the unique biology of the patient, i.e., autologous.

We believe our personalized biologics approach provides distinct advantages for creating cell and gene therapies: Localized administration avoids side effects typically associated with systemic therapy; use of autologous fibroblasts reduces rejection concerns because the cells come from the patient; and genetic modification of fibroblast cells ex vivo enables testing for safety and confirmation of protein expression levels prior to administration to the patient. In addition, our gene-therapy product candidates — which are being developed in collaboration with Intrexon Corporation (NYSE:XON) — typically focus on monogenic or single-gene disorders with a known mechanism of action. This approach enables us to target and treat the underlying cause of disease, not just symptoms, as well as offer the potential for a greater degree of predictability and effectiveness.

TWST: Is there any competition for your product candidates at this time?

Mr. Pernock: Currently, we believe there is no direct competition for our product candidates. azficel-T is being developed to treat vocal cord scarring resulting in chronic or severe dysphonia. Current treatments for vocal cord scarring, which include voice therapy and surgery through the use of injection — collagen, fat, calcium, hyaluronic acid — or implant — PTFE, silastic — only address the symptoms of this condition.

FCX-007 is being developed for the treatment of recessive dystrophic epidermolysis bullosa, also known as RDEB. Current treatments for RDEB, which include bandaging, antibiotics, feeding tubes, and surgery — hand and esophageal — only address the symptoms of this disorder. There are currently no products approved by the U.S. Food and Drug Administration, or FDA, for the treatment of RDEB.

FCX-013 is being developed for the treatment of linear scleroderma. Current treatments for linear scleroderma, which include systemic or topical corticosteroids, UVA light therapy and physical therapy, only address the symptoms of the disorder. There are currently no products approved by the FDA for the treatment of linear scleroderma.

TWST: Tell us about the use of Fibrocell's autologous fibroblast technology in the aesthetics market and how azficel-T is being leveraged in other therapeutic areas.

Mr. Pernock: LAVIV — azficel-T — was approved by the FDA in June 2011 for the improvement of the appearance of moderate to severe nasolabial fold, or smile line, wrinkles in adults. LAVIV utilizes our proprietary autologous fibroblast technology. This technology is the basis of our personalized biologics platform. Fibroblasts, the

most common cell in skin and connective tissue, are responsible for synthesizing extracellular matrix proteins, including collagen and other growth factors, that provide structure and support.

"We have two gene-therapy product candidates in preclinical development and a third gene-therapy program in the research phase. Our lead gene-therapy product candidate, FCX-007, is in late-stage preclinical development for the treatment of recessive dystrophic epidermolysis bullosa, or RDEB"

To create LAVIV, a physician takes a small skin sample from behind the patient's ear and sends it to our FDA-inspected cGMP cell manufacturing facility where, using our proprietary autologous fibroblast technology, the fibroblast cells are extracted from the patient's skin sample and multiplied into millions of new, collagen-producing fibroblasts to make LAVIV. The product is then shipped to the physician for injection into the patient's smile lines.

In 2013, we shifted our strategic focus away from the aesthetics market. We are leveraging our FDA-approved Biologics License Application — BLA — for LAVIV to investigate the use of azficel-T in other therapeutic areas. As a result, we no longer actively market or promote LAVIV, but we continue to maintain our FDA-inspected cGMP manufacturing facility, and to accept and fill prescriptions for LAVIV.

Currently, we are investigating azficel-T in a Phase II clinical trial for the treatment of vocal cord scarring resulting in chronic or severe dysphonia. This is our most advanced development program. Vocal cord scarring is caused by damage to the fibroblast layer of the vocal cords, which reduces vocal cord elasticity and airflow, affecting voice tone and volume. This reduction in vocal capacity is referred to as dysphonia, severe cases of which can lead to a total loss of voice.

TWST: Talk about the results of the Phase I trial for azficel-T for the treatment of vocal cord scarring, as well as the status of the Phase II clinical trial and next steps toward commercialization in the U.S.

Mr. Pernock: azficel-T is in development to treat patients suffering from vocal cord scarring that is either idiopathic or age-related, of which we estimate there to be approximately 64,000 in the U.S. This potential indication presents a unique opportunity for us. By restoring the extracellular matrix to repair damage to the fibroblast layer of the vocal cords, we believe azficel-T will improve voice quality in these patients. This program is being conducted under an Investigational New Drug application, or IND, that cross-references our FDA-approved BLA for LAVIV, which allows us to leverage the safety, chemistry and manufacturing data contained in the BLA.

We did a five-patient Phase I pilot study examining the safety and efficacy of azficel-T injections for patients who had failed to improve following currently available treatments. The data from this trial showed a positive trend of sustained improvement in a majority of patients. azficel-T was well-tolerated in this study, and no serious adverse events were reported. Subsequently, a Phase II clinical trial was initiated.

This Phase II study is a double-blind, randomized, placebo-controlled trial in over 20 patients designed to test the safety and efficacy of azficel-T in subjects with chronic or severe dysphonia caused by idiopathic vocal cold scarring or atrophy. Primary efficacy is being assessed at four months following the last treatment on three different scales: Voice Handicap Index; mucosal wave grade; and GRBAS, or grade, roughness, breathiness, asthenia and strain. We have completed dosing and expect to announce primary endpoint results in the second quarter of 2016, a significant milestone for Fibrocell and patients.

TWST: What is the potential benefit of pursuing this indication for azficel-T?

Mr. Pernock: Chronic dysphonia is a serious and debilitating condition. By pursuing this indication for azficel-T, we have an opportunity to help people whose ability to speak has been significantly compromised or lost. Our hope is to restore their voices.

TWST: In addition to azficel-T for vocal cord scarring, what other product candidates are in your pipeline, and what is their status?

Mr. Pernock: We have two gene-therapy product candidates in preclinical development and a third gene-therapy program in the research phase. Our lead gene-therapy product candidate, FCX-007, is in late-stage preclinical development for the treatment of recessive dystrophic epidermolysis bullosa, or RDEB. RDEB is a congenital, progressive, devastatingly painful and debilitating genetic disorder that often leads to death, and is the most severe form of dystrophic epidermolysis bullosa. RDEB is caused by a mutation of the COL7A1 gene.

The COL7A1 gene encodes for type VII collagen, or COL7, a protein that forms anchoring fibrils. Anchoring fibrils hold together the layers of skin, and without them, skin layers separate, causing severe blistering, open wounds and scarring in response to any kind of friction, including normal daily activities like rubbing or scratching. Children who inherit this condition are often called "butterfly children" because their skin can be as fragile as a butterfly's wings. We estimate that there are approximately 1,100 to 2,500 people suffering from RDEB in the U.S. Current treatments for RDEB, which include daily bandaging, hydrogel dressings, antibiotics, feeding tubes and surgery — hand and esophageal — only address the symptoms of the disorder.

FCX-007 is an autologous fibroblast cell genetically modified to express COL7 for localized treatment of RDEB. FCX-007 is administered via injection to the dermal layer of the skin where the genetically modified fibroblast cells will produce COL7 to promote the formation of anchoring fibrils to aid in wound closure and prevention of wound recurrence. FCX-007 has received orphan drug designation as well as rare pediatric disease designation from the FDA. We are very excited about FCX-007, and subject to FDA allowance of our IND for FCX-007, we expect to initiate human clinical trials in the second quarter of 2016. This is an exciting initiative that we are very passionate about.

Our second gene-therapy product candidate, FCX-013, is in preclinical development for the treatment of linear

scleroderma. Linear scleroderma is a localized autoimmune skin disorder that manifests as excess production of extracellular matrix, specifically type I collagen and type III collagen, resulting in fibrosis and linear scars. The linear areas of skin thickening may extend to underlying tissue and muscle in children, which may impair growth and development. Lesions appearing across joints can be painful, impair motion and may be permanent. Current treatments for linear scleroderma, which include systemic or topical corticosteroids, UVA light therapy and physical therapy, only address the symptoms of the disorder. We estimate the U.S. population of patients who have linear scleroderma over a major joint and exhibit severe joint pain to be approximately 40,000.

"By combining our expertise and technologies, we are genetically modifying autologous fibroblast cells to express targeted proteins in order to address the underlying cause of debilitating diseases of the skin, connective tissue and joints."

FCX-013 is an autologous fibroblast cell genetically modified to express a protein to breakdown collagen accumulation at the site of the localized disease. FCX-013 incorporates Intrexon's proprietary RheoSwitch Therapeutic System technology; the RTS biologic switch is activated by an orally administered compound to control protein expression. FCX-013 is administered via injection under the skin at the location of the fibrosis where the genetically modified fibroblast cells will produce a protein to break down excess collagen accumulation. Once the fibrosis is resolved, the patient will stop taking the oral compound, which will stop further production of the subject protein by FCX-013. We successfully completed a proof-of-concept animal study for FCX-013 in the first quarter of 2016 and expect to file an IND with the FDA in 2017. We also plan to seek orphan drug designation for FCX-013.

Our third gene-therapy program is focused on the treatment of arthritis. This program is in the research phase and is also being undertaken in collaboration with Intrexon. Our goal is to deliver a protein therapy locally to the joint to provide sustained efficacy while avoiding key side effects typically associated with systemic therapy.

Arthritis is a broad term that covers a group of more than 100 different types of diseases that affect the joints, as well as connective tissues and organs, including the skin. According to the Centers for Disease Control and Prevention, arthritis — characterized by joint inflammation, pain and decreased range of motion — is the United States' most common cause of disability, affecting more than 52 million adults as well as 300,000 children at a cost exceeding $120 billion. The recent expansion of our collaboration with Intrexon to develop a new gene-therapy program for the treatment of arthritis has the potential to further demonstrate the power of our combined technology platforms and enable us to contend for leadership in a prominent therapeutic category.

TWST: Describe Fibrocell's collaboration with Intrexon and how synthetic biology is being applied to the development of your gene-therapy product candidates.

Mr. Pernock: We have entered into multiple collaborations with Intrexon. Our collaborations bring together Fibrocell's expertise in manufacturing autologous cell-based therapies with Intrexon's expertise in synthetic biology. By combining our expertise and technologies, we are genetically modifying autologous fibroblast cells to express targeted proteins in order to address the underlying cause of debilitating diseases of the skin, connective tissue and joints.

Through our collaboration with Intrexon, we have access to: Intrexon's proprietary vector technology, which is designed to facilitate the assembly and delivery of the necessary target gene constructs for delivery to autologous fibroblast cells — access to this technology allows us to rapidly screen and construct genetic therapeutic solutions — and Intrexon's proprietary RheoSwitch Therapeutic System, or RTS, technology. The RTS biologic switch is activated by an orally administered compound that provides the ability to control the level and timing of protein expression in those diseases where such control is ideal.

We are developing our two gene-therapy product candidates, FCX-007 for the treatment of RDEB and FCX-013 for the treatment of linear scleroderma, in collaboration with Intrexon, and we have a third gene-therapy program focused on the treatment of arthritis in the research phase. We believe our collaborative approach with Intrexon offers a powerful platform for creating potentially transformative gene therapies.

TWST: Have you engaged in any new initiatives recently?

Mr. Pernock: In December 2015, Fibrocell and Intrexon entered into a new collaboration for the development of genetically modified fibroblasts to treat chronic inflammatory and degenerative diseases of the joint, including arthritis and related conditions. Through this collaboration, our autologous fibroblast technology will be combined with Intrexon's cellular engineering to develop localized gene therapies. Our goal is to deliver a protein therapy locally to the joint, providing sustained efficacy while avoiding key side effects typically associated with systemic therapy.

TWST: What is Fibrocell's primary business objective? What are key upcoming milestones?

Mr. Pernock: Our primary objective is to develop and commercialize transformational therapies for diseases affecting the skin, connective tissue and joints to improve the lives of patients and their families. Key elements in support of our objective are: leveraging our FDA-approved BLA for azficel-T to investigate and seek approval for additional therapeutic indications, including vocal cord scarring resulting in chronic or severe dysphonia; advancing our gene-therapy product candidates, FCX-007 and FCX-013, into human clinical trials; advancing our gene-therapy program focused on arthritis through research and into preclinical development; and leveraging our FDA-inspected cGMP manufacturing facility in Exton, Pennsylvania, and our expertise in cell therapy manufacturing to advance the development of our autologous cell and gene-therapy pipeline.

There are a number of important milestones that we have already or expect to achieve this year. In the first quarter of 2016, we completed the proof-of-concept animal study for FCX-013, our gene-

therapy product candidate for the treatment of linear scleroderma. We also plan to achieve two major milestones by the end of the second quarter, including initiating Phase I/II human clinical trials for FCX-007, our gene-therapy product candidate for the treatment of RDEB, and reporting Phase II clinical data for azficel-T for the treatment of vocal cord scarring resulting in chronic or severe dysphonia. In addition, we expect to continue preclinical studies for FCX-013 this year and anticipate submitting an IND to the FDA in 2017.

TWST: What do you want the public to know about Fibrocell?

Mr. Pernock: This is an exciting and productive time at Fibrocell, as cell and gene therapies across the industry are attracting significant investment and have the potential to transform the future of medicine. We are uniquely positioned to be a leader in this remarkable and growing field as we continue to advance our product candidates. We have a distinctive approach to product development based on our proprietary autologous fibroblast technology. By extracting fibroblast cells from a patient's own skin, we create localized therapies that are compatible with the unique biology of each patient and have the potential to address the underlying cause of disease. We are encouraged by our progress and look forward to achieving milestones that bring us closer to delivering personalized cell and gene therapies that could be transformative for patients and families living with debilitating diseases affecting the skin, connective tissue and joints.

TWST: Thank you. (KJL)

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