



Developing Diagnostics and Therapeutics For Musculoskeletal Disease

EXECUTIVE SUMMARY

Background

In the U.S., over 30 million people are treated for back pain every year, and painful osteoarthritis (OA) affects nearly 27 million people. Back pain is the #1 cause of missed work and the #1 healthcare expense in our country. Joint pain and OA account for millions of doctor office visits each year, and are rapidly rising as the average life expectancy increases. In all, musculoskeletal disease burdens our nation with human suffering, lost productivity, missed work, and excessive medical expenses.

Business Summary

Cytonics has developed protein-based diagnostics and therapeutics for orthopedic pain. We have discovered a unique "bio-marker" that can assist physicians in improving patient outcomes by pinpointing the source of orthopedic pain. We have also developed a range of therapeutic products for the treatment of osteoarthritis, back, and joint pain. Cytonics research and development lab is located in Jupiter, FL with a team of scientists working to discover and develop novel products for the treatment of musculoskeletal disease.

Our Mission is...

To be the leader in diagnostic products for musculoskeletal disease, and to develop highly effective biotechnology based treatments for osteoarthritis, back, and joint pain.

Diagnostic Products

Our patented FACT™ diagnostic assay measures the presence of the Fibronectin-Aggregan Complex (FAC) in a fluid specimen taken from patients with spine or joint related pain. FACT is a Lab Developed Test (LDT) that is processed in Cytonics' CLIA certified lab. The company has recently launched the FACT Molecular Discography and the Joint Diagnostic products in the US market.

FACT Clinical Significance

Physicians commonly use MRI imaging to identify orthopedic abnormalities. However, MRI has limitations. Many patients have "normal" looking anatomy following a traumatic injury even though degenerative enzymes may be at work causing pain and slowly destroying their joint. Additionally, patients often have

non-painful abnormalities that have the same appearance under MRI as painful conditions. This makes it difficult for surgeons to diagnosis the source of pain and to make decisions on the best course of treatment. The limitations of MRI can lead to misdiagnosis, ineffective surgeries and other inappropriate treatments, leaving patients to continue to suffer in pain, despite the best effort and intentions of their physicians.

Research has shown that an inflammatory cascade of proteins causes back and joint pain. Our FACT assay detects a unique bio-marker (FAC) in this cascade allowing physicians to pinpoint and treat the source of pain.

Therapeutic Products

Cytonics is developing the next generation in autologous treatments for osteoarthritis, back and joint pain. Based on Cytonics' in-depth knowledge of the pain cascade and our discovery of FAC, we have developed a treatment that inhibits cartilage degeneration and prevents the formation of FAC. Our APIC™ System utilizes a unique centrifugation and filtration process to concentrate plasma proteins from a patient's own blood. APIC has been shown to slow the progression of osteoarthritis in preclinical models. We received 510(k) clearance from the FDA in 1Q14 for our APIC PRP System and we will submit an IND application for an APIC clinical trial in 2Q14, with support from our regulatory affairs counsel, Hogan Lovells.

Cytonics is also developing recombinant protein therapies for treating OA, back, and joint pain. We have developed unique recombinant protein compounds that have tremendous potential for treating patients with musculoskeletal disease. We plan to have these therapies in preclinical testing in 2014.

Intellectual Property

Cytonics has invested over \$500K in patent development, and has filed numerous domestic and international patent applications. We have obtained U.S. Patent #7,709,215 and #8,338,572 for diagnostics and have a number of other U.S. and foreign patent applications pending for our diagnostic and therapeutic products. Our patent counsel is Wilson Sonsini Goodrich and Rosati.

Market

We intend to market our products to the more than 50,000 surgeons and physicians that treat patients for osteoarthritis and orthopedic related pain in the U.S. and around the world.

Benefits and Savings

Patients will benefit from the technologies developed by Cytonics with better diagnosis and more effective treatments. Hospitals, health insurance providers, and governments will benefit with improved outcomes and reduced costs for treating musculoskeletal disease.

Research Collaborations

The company has developed relationships with researchers and clinicians at leading institutions around the country including Stanford University, the University of Iowa, and the University of Michigan, as well as at local institutions including the Scripps Research Institute, Florida Atlantic University, and Palm Beach State College. The company has sponsored a research project at Stanford University to study the use of FACT for patients with radiculopathic back pain, the results of which will be published in 3Q14. Our research has resulted in 15 papers that have been accepted for publication in leading US medical journals.

Management Team

Gaetano Scuderi, M.D., President, Chairman
Robert Bowser, Ph.D., Chief Scientific Officer
Lewis Hanna, Ph.D., VP Research & Devel.
Sara Belotto, MBA, Controller

Capitalization

The company has raised over \$15M in funding, including a prestigious \$1.8M grant from the National Institute of Health. An international orthopedic implant company purchased a minority interest in Cytonics in 2011 and made a significant additional investment in 2013. We are currently offering Series B Preferred shares at \$4.00/share to accredited investors. Our corporate and securities counsel is Duane Morris LLP.

Contact Information

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