



## Musculoskeletal Related Conditions

### Overview

Musculoskeletal disorders (MSDs) occur when there are injuries to the joints and the soft tissue that helps move them. These conditions can thus affect joints, muscles, tendons, cartilage, and supporting structures of the upper and lower limbs, neck and back. They can be caused by sudden exertion or prolonged physical factors such as repetition, force, vibration and awkward posture.<sup>1</sup> In essence, the tissues of these structures are working harder than they are designed to.

Common symptoms of MSDs include inflammation, redness, decreased range of motion, loss of function, stiffness, pain and fatigue, among others. Arthritis, carpal tunnel syndrome, tendonitis, bursitis and epicondylitis (tennis and golfer's elbow) and trigger finger (gamer's finger) are some common examples of MSDs.<sup>2</sup>

There are over 100 diseases that affect the joints and surrounding tissue. Arthritis alone affects around 46 million Americans.<sup>3</sup> In general, more than one in four Americans has a musculoskeletal condition that requires medical attention. Though many musculoskeletal conditions can be treated by either a general practitioner or a specialist, the burden of musculoskeletal disease is expected to increase in the next 20 years.<sup>4</sup>

### Musculoskeletal Related Conditions and Regenerative Medicine

Several of the regenerative medicine products currently available on the market are for musculoskeletal disorders. Many ARM members are focusing on developing therapeutic products for musculoskeletal disorders with technologies including both cellular therapies and, synthetic and biomaterial-based products.

**Mesoblast** is developing cellular therapies using their mesenchymal precursor cell (MPC) technology platform to target several musculoskeletal disorders. By injecting MPCs into a degenerated intervertebral disc, they hope to see the replacement of the lost proteoglycan and cartilage that gives the disc its functional properties (which include cushion for stress forces and normal rotation of the spine). The company currently has several clinical studies underway for degenerative disc disease (DDD). Clinical trials for bone fracture repair and arthritis relief are also in the company's development pipeline.

**DiscGenics** is using adult-derived stem cells combined with tissue-engineered technologies to treat patients with DDD. DiscGenics is isolating stem cells from disc tissue and expanding them into cell populations known as Discospheres. These cells have different properties compared to regular MSCs, but the company's research suggests they may in fact be more effective in

their regenerative capabilities for the damaged discs. In late February of 2013, the company announced promising preclinical results, and is currently conducting additional animal studies to support the initiation of human clinical studies.

Histogenics' products are aimed at preventing the effects of cartilage damage by regenerating healthy hyaline cartilage tissue. They are currently developing two products, NeoCart and VeriCart. NeoCart is an autologous engineered neocartilage grown outside the body and used to repair cartilage lesions. Phase 2 trials for NeoCart were recently completed, with positive data trends when compared to microfracture, and Phase 3 trials are currently ongoing. The company hopes to submit VeriCart, a collagen-based scaffold technology, for a CE mark by mid-2013 and gain regulatory approval designation by the end of the year.

ISTO Technologies is targeting orthopedic treatment with both cell-based and biomaterial-based technologies. DeNovo ET is the company's allogeneic living cartilage implant designed to repair and regenerate damaged knee cartilage. The product uses a patented, juvenile cell-based technology which may have superior regenerative

properties compared to adult cartilage cells. ISTO is currently enrolling subjects in a Phase 3 trial of the product for knee repair. They are also exploring the use of these cells in the spine to combat disc damage.

MiMedex Group, Inc. is currently focusing on two musculoskeletal products. CollaFix, a product not yet approved in the U.S., functions as a scaffold that assists the body's ability to generate new tissue. The product is also biodegradable and gradually disappears after the repair is complete. A second product, HydroFix Vaso Shield, is a vessel guard made of the company's proprietary hydrogel material to protect veins and arteries during surgery.

As mentioned earlier, many regenerative medicine products for musculoskeletal conditions are already on the market and in use by medical professionals. Genzyme Sanofi's cell therapy product Carticel has treated thousands of patients with damaged knee cartilage and AlloSource, is developing, processing and distributing allografts (tissue grafts obtained from donors), and currently has over 200 standard and customized allograft products on the market.

## Musculoskeletal Related Conditions: Economic Impact



**132 Million MD Office Visits**  
**29 Million ER Visits**  
**15 Million Out Patient Visits**  
 Musculoskeletal related visits per year.<sup>5</sup>



**\$850 Billion**  
 Estimated annual direct and indirect healthcare cost for musculoskeletal related conditions.<sup>5</sup>



**440 Million Days**  
 Missed work days due to musculoskeletal related conditions.<sup>5</sup>

<sup>1</sup> National Institute for Occupational Safety and Health (NIOSH), "Musculoskeletal Disorders: Program Description," December 18, 2012, Centers for Disease Control and Prevention (CDC) website, [www.cdc.gov/niosh/programs/msd/](http://www.cdc.gov/niosh/programs/msd/)

<sup>2</sup> Mohawk College, "Musculoskeletal Disorder (MSD) Signs and Symptoms," October 30, 2012, Mohawk College website, [www.mohawkcollege.ca/Explore/jobs/currentjobopps/hrstaffservices/OHS/Ergonomics/signsSymptoms](http://www.mohawkcollege.ca/Explore/jobs/currentjobopps/hrstaffservices/OHS/Ergonomics/signsSymptoms)

<sup>3</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA), "Facts about Musculoskeletal Disorders and Arthritis," PhRMA website, [www.phrma.org/research/facts-about-musculoskeletal-disorders-arthritis](http://www.phrma.org/research/facts-about-musculoskeletal-disorders-arthritis)

<sup>4</sup> *The Burden of Musculoskeletal Diseases in the United States* available at [www.boneandjointburden.org](http://www.boneandjointburden.org) (published by The United States Bone and Joint Initiative, 2011)

<sup>5</sup> Penn Center for Musculoskeletal Disorders, "Overview of the Penn Center for Musculoskeletal Disorders," Perelman School of Medicine at the University of Pennsylvania website, <http://www.med.upenn.edu/pcmd/overview.shtml>