

Executive Summary SomaTx Design Inc:

KneeMo®: A Novel System to Address Musculoskeletal Disorders

The Problem:

Musculoskeletal disorders have a substantial and growing societal impact.

- Affects more than one out of every two persons in the United States over age 18, and three out of four over age 65¹.
- Osteoarthritis (OA), among the most common forms of musculoskeletal disorders, accounts for 2.4% of all years lived with disability (YLD) and has been ranked as the 10th leading contributor to global YLDs².
- Approximately 242 million people in the world live with symptomatic and activity limiting OA of the hip and/or knee, accounting for 13 million YLDs².
- Indirect costs due to loss of productivity have been estimated to cost from \$3.4 to \$13.2 billion per year.
- No drugs or treatment has been shown to prevent, stop, or even restrain progression to OA following injury.
- Medications to mitigate musculoskeletal pain have a number of risks (e.g., myocardial infarction)

The Technology:

KneeMo® is a novel non-pharmacological system to address the disability, pain and pathway to disability associated with injury and/or progressive diseases such as osteoarthritis. Specific feature of the KneeMo® include the following:

- Two bands located above and below the knee as well as an App on a smart device (Figure 1.)
- The bands are “smart” in that they are programmed to sense motion during activities and trigger an intermittent vibrational stimulus at specific phases during ambulation.
- The bands communicate using blue tooth to a smart device that adjust vibration intensity and phasing during ambulation.
- An intermittent vibrational stimulus to the skin at the knee to engage properties of the neuromuscular system that gate pain and enhance muscle function during walking.
- It enhances muscle function during ambulation: A condition identified^{3,4,5,6} as one of the critical yet unsolved problems in the treatment of musculoskeletal disorders such as osteoarthritis.
- It has been tested in a clinical trial^{7,8,9} with positive results demonstrating proof of concept by improving muscle function during walking in patients with knee pain.
- It satisfies the conditions for a Class 1 classification and is exempt from premarket notification based on Code of Federal Regulations Subchapter Title 21 H-Medical Device, Part 80 Physical Medical Devices, and Subpart F Physical Medicine Therapeutic Devices.

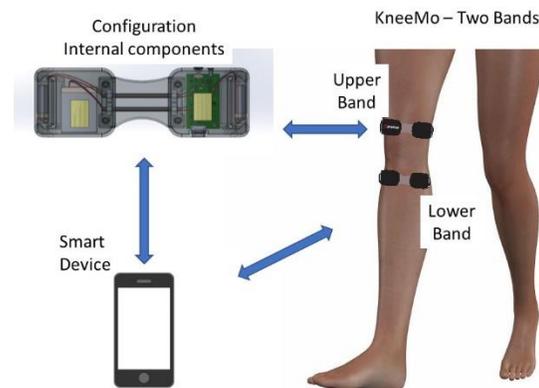


Figure 1 The elements of KneeMo® include bands with internal components, the control vibration activation and communicate with an App and a smart device.

Potential Derivative Products

Given that the system can work autonomously or communicate with a Smart device to enhance the scope of its functions there is a broad scope of potential commercial applications. For example:

- Develop software for communication to cloud (yearly licensed) for AI feedback and evaluation of performance.
- Develop applications for health care providers for enhancing therapy sessions, remote monitoring and in session evaluations.
- Develop application for athletic trainers to enhance training.
- Develop products for other musculoskeletal issues (e.g., back, should hip, elbow, etc.) using derivative technology.

Competition:

Competitive wearable interventions to KneeMo® include commercially- available wearable devices such as, Quell™, Icy Hot SmartRelief™ or Aleve Direct Therapy™. These devices all use transcutaneous electrical stimulation (TENS). There remain questions when evaluating TENS effectiveness relative to a placebo control as assessed by patient- reported outcomes. It has been reported that TENS treatment does not result in an improvement in ambulatory muscle function in patients with knee pathology. The electrical stimulus is often uncomfortable and is not permitted in patients with pacemakers or during pregnancy. The lack of the capacity to improve the ambulatory muscle function as well as the potential risks using TENS begs the need for alternative methods to address restoring ambulatory muscle function in patients with knee pathology.

Intellinetix Wearable Vibration Therapy by BrownMed appears to be a direct competitor. However, this product is marketed as a massage unit to be worn for 45 minutes. There is no intermittency to the product vibration, as a result it is only marketed as pain relief but there is no evidence to support improved mobility. Ratings on the Vibration therapy results were poor. No other technologies are known to exist in the market.

The Pricing, nature of sale and distribution of consumer grade TENS products provides a basis for establishing the business model for the SomaTX products TENS units range in retail price between \$25.00 and \$350.00 and are sold through traditional retail outlets such as Walmart, CVS and Walgreens and E-Commerce locations such as Amazon and Google. TENS units may also be used at physical therapy centers and are prescribed by physicians.

What is Next?

- Test a design for manufacturing model of KneeMo® that has been developed and is nearly ready for the first production run e.
- Develop pathways to quickly commercialize the device and establish a reputation for a device that is well supported by solid science clinical trials and positive user feedback. Speed of recognition is important since once understood the device could be easily copied by “me too” devices.
- Generate broader awareness of the system by making it available to well-recognized health care providers, research laboratories and athletic professionals that could serve as opinion leaders in promoting the device as well as serving on the advisory board.
- Evaluate e-business (B2C) options – customer service, fulfillment procedures, inventory and supply chain management.
- Evaluate Direct Test (B2B) to medical care providers through Durable Medical Equipment Services (DME) owned by medical practices. – suggested by one of the leading surgeons we contacted as a method to engage health care providers.

In Conclusion:

Considering the need, broad scope of potential customers, low barriers to market and the novel features the system should be attractive to investors, users and possible large companies as partners.

References:

1. The Burden of Musculoskeletal Diseases in the United States (BMUS), 9400 West Higgins Road, Suite 500 Rosemont, IL 60018-4976, United States of America
2. Osteoarthritis: A serious disease, Osteoarthritis Research Society White Paper, December 2016, https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa_serious_disease_121416_1.pdf
3. Anwer S, Alghadir A. Effect of Isometric Quadriceps Exercise on Muscle Strength, Pain, and Function in Patients with Knee Osteoarthritis: A Randomized Controlled Study. *Journal of Physical Therapy Science*. 2014;26(5):745-748.
4. Norden DK, Leventhal LJ, Schumacher HR. Prescribing exercise for osteoarthritis of the knee. *Journal Musculoskeletal Medicine*. 1994;11:14-21.
5. Culvenor AG, Ruhdorfer A, Juhl C, Eckstein F, Elin Øiestad B. Knee Extensor Strength and Risk of Structural, Symptomatic, and Functional Decline in Knee Osteoarthritis: A Systematic Review and Meta-Analysis. *Arthritis Care and Research*. 2017;69(5):649-658.
6. Amin S, Baker K, Niu J, et al. Quadriceps strength and the risk of cartilage loss and symptom progression in knee osteoarthritis. *Arthritis and Rheumatism*. 2009;60(1):189-198.
7. AG Fischer, JC Erhart-Hledik, JL Asay, CR Chu, TP Andriacchi, Utilizing the somatosensory system via vibratory stimulation to mitigate knee pain during walking: Randomized clinical trial *Gait & Posture* 80, 37-43, 2020.
8. AG Fischer, JC Erhart-Hledik, JL Asay, CR Chu, TP Andriacchi, Activating the somatosensory system enhances knee flexion and quadriceps activity during gait and stair climbing, *Osteoarthritis and Cartilage* 27, S63-S64, 2019.
9. AG Fischer, JC Erhart-Hledik, JL Asay, CR Chu, TP Andriacchi, Utilizing the somatosensory system via vibratory stimulation to mitigate knee pain during walking: Randomized clinical trial *Gait & Posture* 80, 37-43, 2020.