E x e c u t i v e M e m o r a n d u m

To: Munevo Executives
From: Massachusetts Maritime Academy IACBE Team
Subject: Munevo Introduction to the United States
Date: November 13, 2019

Introduction

Munevo is a company that offers a smart glass technology, which creates a solution for individuals with disabilities. The incredible technology that Munevo offers lets the user control the wheelchair completely hands free. This is crucial for individuals that are quadriplegic, paraplegic, as well as others with medical conditions such as MS, ALS, and Muscular Dystrophy. Munevo's advancement of technology creates a new form of life for certain people, who were currently struggling with older, obsolete systems. Munevo upholds a key value in safety for users, which is evident through their 'current location function', which allows the user to share their location if an emergency arises.

Problem

As Munevo continues to advance, new market opportunities will become prevalent. Currently, Munevo is available in Germany, Austria, Switzerland, and France. By expanding to the United States, Munevo could open up an opportunity for extensive sales. Proper planning needs to be ensured so that the barriers to entry can be overcome with ease. Challenges faced for entry into the United States include but are not limited to; FDA Regulation, the health care system, competition, marketing, economics, as well as other nominal factors.

Analysis

The Massachusetts Maritime Academy IACBE Team has conducted extensive research for Munevo to eliminate unnecessary risks regarding the entry to the United States. We have analyzed competition, the market, and the economic issues that Munevo will confront. These key factors were thoroughly gone through, as these can make or break an entry into a new market.

The United States currently has twenty three wheelchair producers that make up the market of approximately 2.7 million wheelchair users in the United States. This is not to be confused with the total number of assistive medical device users which is roughly 7.9 million people in the United States.[1] Although the twenty three other manufacturers are not as technological advanced as Munevo, they still hold the majority share of the market, specifically because of price and the capabilities of the device based on the users needs. One of the most advanced chairs in the United States is produced by Whill Wheelchair. Their product has been FDA approved, and sells for roughly $9,999 which brings it much cheaper than Munevo's estimated cost. [2] Whill's chair is driven by an app or joystick which makes Munevo more competitive for people that do not have the capabilities to control a chair like this, or simply want the ease of controlling movement with the glasses.

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[1] U.S Census Bureau, Americans With Disabilities In 2002, 2002, 1
[2] WHILL, FAQs, 2018

The market analysis shows that the United States is the largest market. As mentioned there are currently twenty three competitors, but the technology of Munevo will prevail. Barriers that will be faced are distribution points as well as customer service locations.

The entry into the United States is one of the biggest steps to this launch, but being able to generate revenue is the most important part. One of the bigger questions we can see being asked by potential users is on cost, and will it be covered by their insurance. The obstacle to this is that most citizens of the United States have different insurance plans. Some insurance plans are extremely good, while others cover the bare minimum.

Recommendation

FDA Approval will be the initial step to get Munevo into the United States, which can be seen in enclosure two. By having Munevo Drive classified as a Type 1 medical device, users will be able to cover this under their insurance using HCPCS Code K0898. This code is 'powered wheelchair, not otherwise classified'. Sub codes to K0898 are E2377 and E2376. Under these codes though, coverage is strictly based on an individual basis under the carriers judgment. Without FDA approval, Munevo would not be covered under insurance, so this is why the product has to go through the process. Clinical trials will have to be undergone which can take anywhere between six months to a year. With Munevo's past experience in clinical trials, this process could potentially be sped up.

After FDA Approval, partnerships and distributors need to be placed in strategic locations across the United States. Numotion, a leader in rehabilitation, has approximately 140 locations across the United States. Numotion also specializes in service and repair, which can be crucial towards the customer service aspect. This can create the first starting point to distribution, followed by working with ASL INC another key distributor. Munevo could benefit greatly as well by working with the VA Hospital system because of their 1200 plus facilities across the United States, which can be seen in enclosure one. Other distribution centers in the United States include; Sunrise Medical in California, Binson's Medical Supplies located in Michigan at St Mary Mercy Hospital, Carle Medical Supply in Illinois, and Susquehanna Valley Medical Supply in Pennsylvania. St. Mary Mercy Hospital has a rehabilitation center which specializes in spinal cord injuries and spine disorders. With the alliances between Munevo and the following distributors, a presence could be established from California to Pennsylvania.

Munevo can become involved with other institutions such as Christopher & Dana Reeve Foundation, American Spinal Injury Association, Canadian & American Spinal Research Organization, Mike Utley Foundation, as well as many others. Theses foundations fund research and rehabilitation regarding spinal cord injury. The introduction into anyone of theses foundations could be crucial to Munevo's success. The approval of the FDA, starting clinical trials as soon as possible, and creating strategic partnerships are the greater part of what is recommended by the Massachusetts Maritime Academy IACBE Team.

Enclosures:
(1) "Doing Business with the VA" Reference Guide
https://www.va.gov/osdbu/docs/DoingBusinessWithVA_ReferenceGuide.pdf

(2) FDA "Device Development Process"
https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process