CONTRACT BOOK

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MotorHAT
HAPTIC ASSISTIVE TECHNOLOGY
FOR MOTOR PROSTHETICS

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Biographies

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Abstract

ProHAT is a haptic accessory to an already-fitted lower limb prosthesis that provides somatosensory feedback from the prosthesis to the user. The system consists of a wearable sensor system, implantable electrodes, and a mobile app. The wearable sensor system features pressure, flex, and touch sensors, which collect load, gait, and tactile information along the foot and the leg of the prosthetic limb. The information from the sensor system is transmitted to the implantable electrodes via a wireless transceiver to provide electrical stimulation of the nerves in the user's residual limb for somatosensory feedback. The transceiver also transmits the information to the mobile app, which permits the user to visualize and interact with the data. The user can use the mobile app to optimize prosthesis use and adjust the intensity of electrical nerve stimulation. Through such mechanisms, ProHAT acts as a robust solution that can improve the user's clinical outcomes and quality of life.

Introduction

Lower limb amputations occur much more frequently than most imagine it to be. Every 30 seconds, a leg is amputated somewhere in the world (Caffrey, 2018). Within the US alone, over 2.1 million individuals are currently living with a loss of limb, and 185,000 new lower-limb amputations are performed each year (Access Prosthetics, 2017).

A majority of these amputations can be attributed to dysvascular causes like diabetes; over 85% of lower limb amputations are associated with diabetic foot ulcers (Access Prosthetics, 2017). Individuals with diabetes are at higher risk of developing foot ulcers due to reduced blood flow to the lower limbs. The presence of neuropathy makes ulcers more difficult to detect in individuals with diabetes and significantly increases the likelihood of tissue infection or death at the site of the ulcer. Studies have found that 5-24% of diabetic foot ulcers lead to amputation within 6-18 months of initial evaluation (Alexiadou and Doupis, 2012).

Given such associations between diabetes and lower limb amputations, the rapid growth in the prevalence of diabetes is highly alarming. The number of individuals diagnosed with diabetes grew by over 370% between 1990 and 2015 (CDC, 2017) and is projected to reach 435 million by 2030 (Access Prosthetics, 2017). The upward surge in the prevalence of diabetes has been accompanied by similar trends in the frequency of lower limb amputations: there was a 24% increase in the number of amputations caused by diabetes between 1988 and 2009 (Access Prosthetics, 2017), and the number of individuals living with limb loss in the US is projected to reach 3.6 million by 2050 (Ziegler-Graham et al., 2008).

There are prosthetic solutions currently available in the market for use by individuals with lower-limb loss. However, they fail to satisfy the needs of lower limb prostheses users with diabetes. First, prosthetic solutions are expensive. The price of lower limb prostheses typically ranges from $5,000-120,000 (McGimpsey and Bradford, 2017; Birnbaum, 2016). As lower limb prostheses have a limited life span of 3-5 years (ABC News, 2013), the lifetime costs for the loss of a single leg sum up to over $1.4 million (Blough et al., 2010), which pose a crippling financial burden to patients with diabetes who already face over $100K in lifetime expenditures associated with diabetes care (Modern Healthcare, 2018). Second, all available solutions are purely mechanical in function and lack sensory feedback capacities. Sensory deprivation in the lower limbs is associated with posture, balance, and gait problems and cause pain and injuries such as cumulative trauma disorder and arthritis in over 80% of lower limb prostheses users (LaRaia, 2010). Lack of sensory feedback has further been linked to sustained phantom limb pain and increased physical and mental demands during limb usage (GEN, 2019). Third, existing solutions neglect the existence of neuropathy in individuals with diabetes. Neuropathy makes it difficult for patients to detect tissue damage in the residual limb or the development of open-wound sores in the intact limb. Such loss of sensory capacities leads to amputation of the

second leg within 2-3 years in up to 55% of patients who have had lower limb amputations (Amputee Coalition, 2020). Such findings show that sensory capacities in the foot and the lower leg are necessary to prevent further amputations after the initial limb loss. To address the shortcomings of existing prosthetic solutions, lower limb prostheses users with diabetes need access to a cost-effective means to provide somatosensory feedback from the prosthesis to the residual limb for improved clinical outcomes and quality of life.

Field Survey

To quantify the size of the clinical problem, we performed market sizing estimations using the current diabetes patient population size, incidence statistics of lower limb amputations, and prostheses usage rates (Amputee Coalition, 2020; Access Prosthetics, 2017; Azura Vascular Care, 2017; Raichle et al., 2009). There are an estimated 552,000 lower limb prostheses users with diabetes within the US. This number is projected to grow by an estimated 113,000 in 2021. If the number of patients with diabetes and the number of lower limb amputations associated with diabetes continues to grow at the current growth rates, there will be a total of approximately 1.35 million lower limb prostheses users with diabetes within the US by 2025. This number will rise further to an estimated 3.11 million by 2030.

A field survey of the market shows that there are three major types of commercially available prosthetic solutions for lower limb amputations: passive prostheses, mechanical prostheses, and microprocessor prostheses. All three types are purely mechanical in function and, as previously described, fail to address the needs of lower limb prostheses users with diabetes. SENSY by SensArs Neuroprosthetics is a fourth type of solution that is currently in development. As a prosthetic device, it uses a sensor system to collect sensory information from the sole and the knee. The collected information is then transmitted to implanted electrodes via cables to provide nerve stimulation. Despite its novel sensory capacities, SENSY also is insufficient for use by lower limb prostheses users with diabetes. Most amputations due to diabetes are below-the-knee, but SENSY is designed for use by transfemoral amputees. As its sensor system is directly incorporated into an above-the-knee prosthetic limb, the user must entirely replace their prosthetic leg to utilize SENSY, which leads to additional costs associated with new prosthesis purchase and fitting. Furthermore, SENSY does not provide sensory feedback from the leg, does not use a wireless mode of signal transmission, and lacks a user interface. A comparison of solution performances with regards to key design features is summarized in the following table:

	Price	Motor function restoration	Somatosensory function restoration	Versatility / adaptability
Our Solution (ProHAT)	**Low:** Approx. $400 for foot component & $250 for leg component	**Variable:** Can be used in conjunction with an already-fitted prosthesis	**High:** Load, gait, and tactile information along the sole & the leg transmitted wirelessly to implanted electrodes to provide nerve stimulation, stimulation levels can be modulated on a mobile app	**High:** Separable foot & leg components can be used with a wide range of prostheses designs & levels of amputations
Passive prostheses	**Medium:** Approx. $1,000 - $10,000	**Low:** No actuation, mostly cosmetic in function	**None**	**Medium:** Offered for a range of different levels of amputations
Mechanical prostheses	**High:** Approx. $5,000 - $15,000	**Medium:** Some surface adaptation, limited degrees of freedom	**None**	**Medium:** Offered for a range of different levels of amputations
Microprocessor prostheses	**High:** Approx. $20,000 - $120,000	**High:** Movement control, surface adaptation, higher degrees of freedom, resemble the natural movement	**None**	**Medium:** Offered for a range of different levels of amputations
SENSY by SensArs Neuro-prosthetics	**Unknown**	**Medium:** Similar to mechanical prostheses with some surface adaptation, the motion may be partially limited by cables used for signal transmission	**Medium:** Load & gait information from sole and knee motion information from electric knee joint transmitted to implanted electrodes along cables to provide nerve stimulation	**Low:** Sensors integrated to the sole, only for transfemoral amputations

The findings of the field survey suggest that there are no competitors for our solution currently in the market or in development.

Patent Survey

Several extensive searches through patents and literature failed to reveal any similar assistive haptic technology for lower limb prostheses users with diabetes. As such, we believe that our solution offers a novel opportunity and is eligible for patenting. The most relevant patents are as follows:

WO2015097623 A1 Bidirectional limb neuroprosthesis

> Integrated neuroprostheses that provide bidirectional control and sensory feedback in upper and lower limb amputees. The system uses electrodes to read in EMG signals and uses the decoded signal to guide the actuation of the

prosthesis. Force, pressure, position, and angular sensors embedded in the finger, fingertips, palm, joints, or foot of a prosthetic limb detect and send stimulation signals to the nerves in a residual limb via intrafascicular electrodes in the residual limb or targeted muscle reinnervation. The type, strength, location, and spatial extension of the stimulation delivered are regulated by a predetermined transfer function.

US8323354 B2 Instrumented prosthetic foot

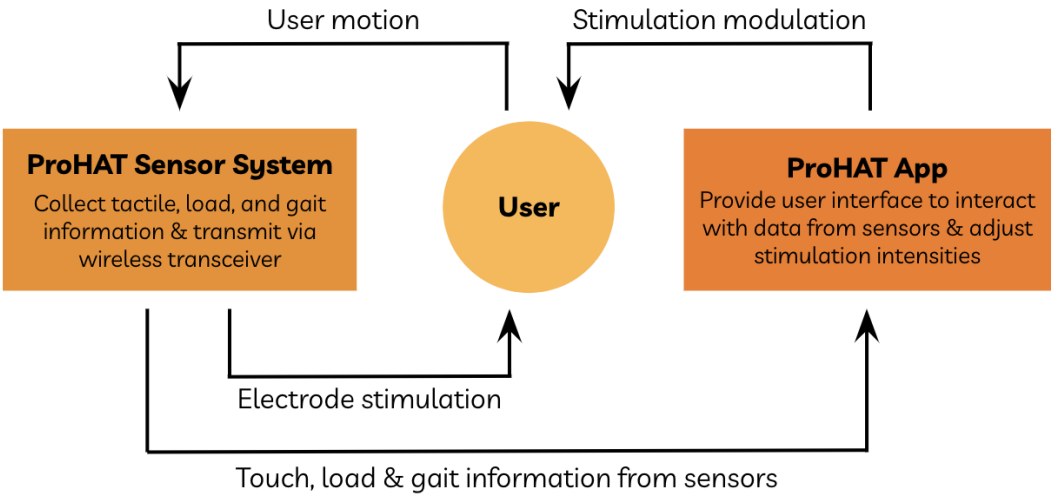
An instrumented prosthetic foot is used in conjunction with actuated leg prostheses, controlled by a controller. A connector is used to connect the instrumented prosthetic foot to the prosthetic leg. An ankle structure is connected to the connector and a ground engaging member is connected to the ankle. Sensors are implemented to detect changes in weight distribution along the prosthetic foot and the data is transmitted from the sensors to the controller.

US0108926 A1 Apparatus and method of implantable bidirectional wireless neural recording and stimulation

A device and method that is used in bi-directional neural recording and stimulation and is specifically used in neuroprostheses. This device can communicate with other neural interfaces and/or external controllers wirelessly. The stimulator is implantable and possesses an ultrasonic secondary battery charging system. The device can wirelessly send trigger pulses to the fully implanted stimulator to restore functions.

Product Description

ProHAT is a versatile, cost-effective accessory to already-fitted lower limb prostheses that can provide somatosensory feedback from the prostheses to users. It achieves this through the integration of a sensor system, mobile app, and implantable electrodes. The sensor system uses a unique arrangement of pressure, flex, and touch sensors that optimizes sensitivity to stimuli. The mobile app receives data from the sensor system via a wireless communication system and provides an interface through which the user can visualize the data and manipulate stimulation levels. The implanted electrodes use the load, gait, and tactile information from the sensor system and modulatory signals from the mobile app to provide appropriate electrical stimulation of the nerves in the residual limb to retrieve sensations. The ProHAT workflow is summarized in the following flow diagram:

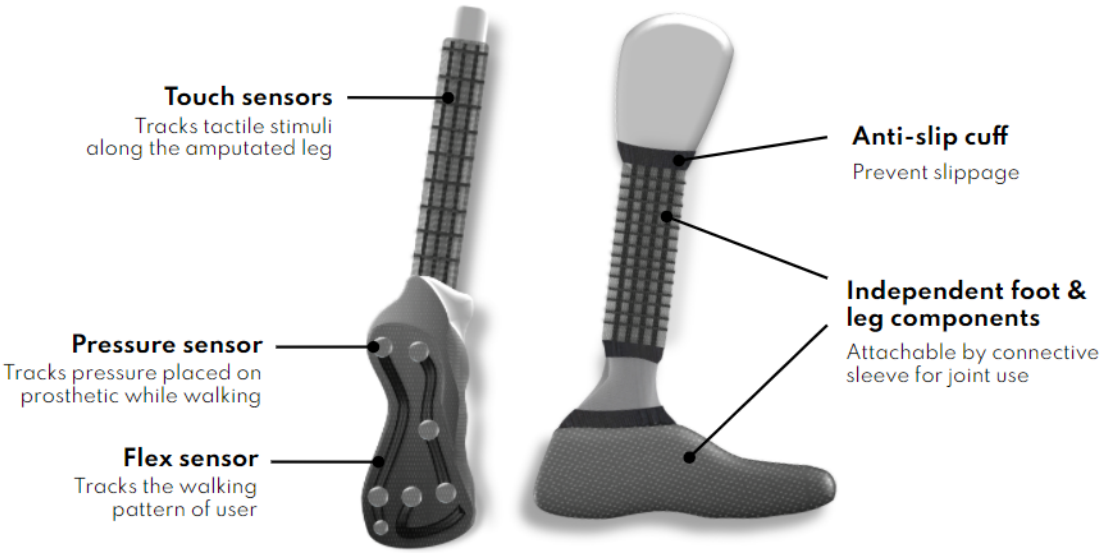


As you can see from the flow diagram, the entire system functions in a user-centered manner, and it is flexible to changes based on the user's needs. ProHAT offers an affordable, adaptable, and customizable solution that lower limb prostheses users with diabetes can easily access, adapt to a wide range of prostheses designs, and customize for personalized user experiences.

Design

The ProHAT sensor system employs an array of sensors to capture sensory stimuli from the environment and provide relevant load, gait, and tactile feedback to the user. There are two separable components to the sensor system — the foot and the leg components. Users with amputations at the foot level can use the foot component

independently; users with higher-level amputations can attach the foot and the leg components with a connective sleeve for joint use. Both components feature anti-slip cuffs at the edges to stabilize the sensors and prevent slippage.



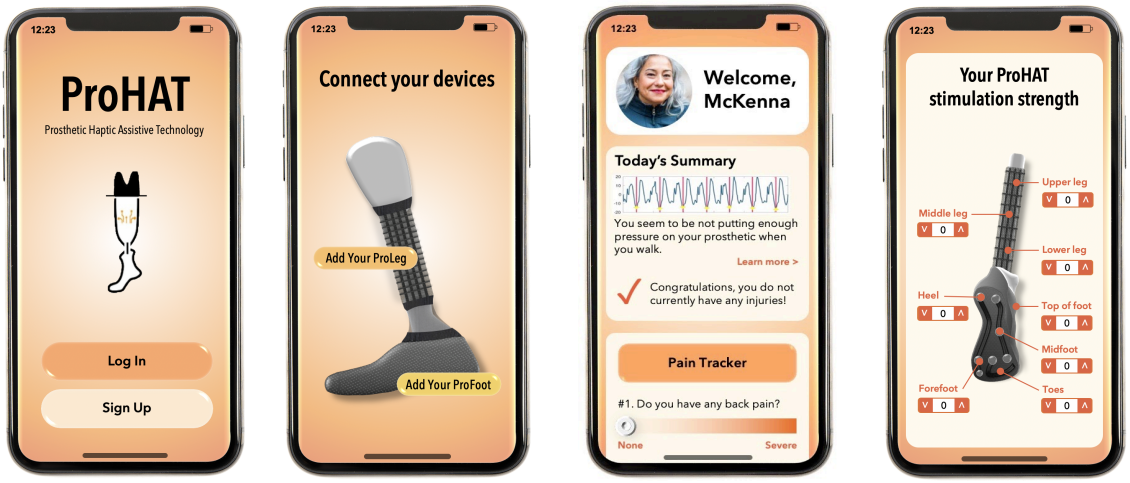
As shown in the diagram above, the foot component implements a network of pressure and flex sensors. The pressure sensors are located along the parts of the foot that are in contact with the ground the most (and thus experience the most load) during the range of natural limb motion. These sensors track the amount of load placed on different parts of the sole during use. The flex sensors, on the other hand, are located along parts of the foot that experience the most stress or strain during the range of natural limb motion. These sensors detect and track the gait patterns of the user.

The leg component implements touch sensors in a grid configuration. The grid placement of the sensors enhances stimulus localization capacities and increases tactile sensitivity through the co-activation of intersecting sensors. The touch sensors detect tactile stimuli along the leg of the prosthesis.

The load, gait, and tactile information collected by the sensors are passed through an algorithm to extract stimulation amplitudes, frequencies, and types appropriate for the detected stimuli. A wireless transceiver then transmits the extracted information to implanted electrodes in the residual limb to provide electrical nerve stimulation.

The sensory information from the sensor system is also transmitted to the mobile app for the visualization of data and the adjustments of feedback stimulation. Once the sensors are connected, the user can use the app to interact with the real-time pressure

and tactile data and track pain points associated with prosthesis use. The app sets up daily goals and suggestions for the user to better utilize his or her prosthesis based on the data from the sensor system and the pain tracker. The app can also be used to adjust the intensity of stimulation from various sensors along the lower limb prostheses. Some sample views of the app are provided below:



The ProHAT design successfully addresses the needs of lower limb prostheses users with diabetes. It is offered at a low cost (see "Business Model" for specifics) and provides the user with relevant somatosensory information that the user desires to receive. Through the mobile app, ProHAT enables users to track not only their prosthetic usage trends but also their perceived pain during prostheses usages, which reduces negative clinical outcomes associated with prosthesis use and diabetic neuropathy. The system itself is designed for use by patients with below-the-knee amputations, and the waterproof, stretchable fabric of the sensor system enables the user to employ ProHAT as an accessory on a wide range of already-fitted lower limb prosthetic devices.

Intended Use

ProHAT is intended to function as a low-cost accessory to already-fitted lower limb prostheses. It should be used to detect load, gait, and tactile information from the prostheses and generate appropriate electrical nerve stimulation through implanted electrodes. The leg and foot components of the sensor system can either be used independently or together depending on the level of amputation, but the mobile app should be used with the use of either component of the sensor system. The foot and leg components of the sensor system can be easily slipped on and off the user's prosthetic

limb as necessary. ProHAT can also be used in rehabilitation settings to help increase prosthesis acceptance and decrease phantom limb pain in the user.

Users should be fitted with the solution in a clinical setting so that a medical professional can help establish appropriate baseline settings (i.e. stimulation intensity, thresholds of natural load or flex stimuli, thresholds of noxious tactile stimuli, etc.). After fitting, ProHAT can be used in everyday settings without oversight.

Regulatory Issues

Although ProHAT functions as an integrated system, the individual components face significantly different regulatory issues. The mobile app is not classified as a medical device and does not have to undergo FDA approval, but it will have to be thoroughly tested and evaluated for user data protection and cybersecurity. The sensor system is constructed from biocompatible materials, but, as it incorporates Bluetooth signal transmission and generates electrical currents, it needs to undergo the FDA approval process as a Class II medical device for safety and compliance. 510(k) program would be necessary. The implanted electrodes, as an implanted device with the potential to present an unreasonable risk of illness or injury, is a Class III medical device. As such, it must undergo the stringent, costly Premarket Approval process. To avoid this, we may partner with producers of implantable microelectrodes or research labs developing neuroprostheses. We also may explore other forms of feedback channels such as vibrotactile feedback and externally-worn microelectrode bands as these would be classified as Class I or II medical devices and require less stringent regulatory processes.

Elevator Pitch

Imagine waking up one day to find that you've lost all sensation in your lower leg. It is still attached to your body, but the utter loss of sensation will make you feel strangely alienated from your leg. Such loss in the intact sense of "self" is the reality that over 1 million lower limb prosthetic users face every day. Prosthetics partially restore the mechanical functions of the lower limb, but the loss of sensory information creates gait and balance problems and increases the rate of injury, discomfort, and pain in prosthetic leg users. Such clinical consequences decrease the quality of life and potentially lead to the loss of a second limb in lower limb prostheses users.

We, at MotorHAT, seek to provide a cost-effective solution to this issue. We present ProHAT, a novel assistive technology that enables patients to recover load, gait, and

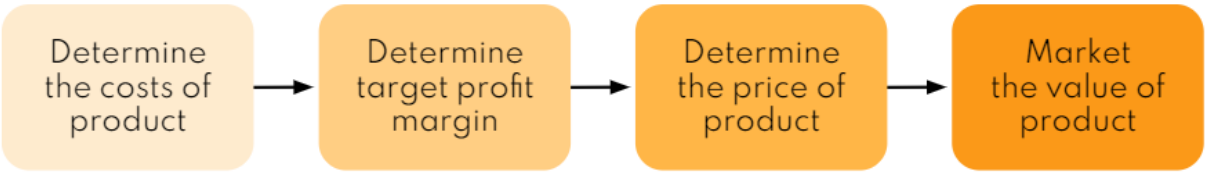
tactile information from the prosthetic limb through direct, wireless stimulation of the nerves in the residual limb with implantable electrodes. With an adjunct smartphone application that allows patients to interact with the collected information and control the stimulation levels, ProHAT will stand out in the market as the only sensory restorative system that can be used in conjunction with already-fitted prosthetic legs.

Dear investors, we present to you an opportunity to invest in our company, profits, and vision. We hope that you will join us on our mission to deliver next-generation sensory rehabilitation technology to prosthetic leg users. Thank you for your consideration.

Logo

Business Model

We will be using a cost-based model for our product. This model is described below:



Since the foot and the leg components of our system are designed for independent use, we plan on selling the foot and leg components as independent products. Access to the mobile app will be provided free of charge with the purchase of either component. Based on current cost estimates, the projected price for the initial purchase is $400 for the foot component (since it is more technologically complicated and contains more sensors) and $250 for the leg component. We project that these prices will yield over a 20% profit margin. We will offer discounted prices for replacement purchases at $300 for the foot component and $200 for the leg component.

Given the novelty of ProHAT, we expect initial user acceptance to be slow and focused on new lower limb prosthesis users with diabetes. As such, we estimate that our initial market share will be limited to approximately 25% of the new lower limb prosthesis user population with diabetes. We will expand our market share into the existing lower limb prosthesis user population through extensive marketing efforts and partnerships with diabetes clinics, insurance companies, and lower limb prostheses providers. Since there are no competitors currently in the market or under development, we believe that we will be able to acquire about 45% of the total market share by 2030. Our projected revenue estimates are as follows:

Year	# of Lower Limb Prosthesis Users with Diabetes (M)	# of Orders (M)	Projected Revenue ($M)
2022	0.81	0.21	110.43
2024	1.08	0.34	177.14
2026	1.52	0.55	290.85
2028	2.26	0.94	494.03
2030	3.11	1.44	757.05

Financial Plan (2021-2023)

Expenses	Cost
Operations Personnel: Engineers & physicians Office & lab space Equipment	$1,000,000
Research & Development Product development Verification & validation testing Clinical trials & pilot studies	$200,000
Regulatory FDA applications Regulatory compliance lawyer	$50,000
IP Development Patent applications Patent lawyer	$10,000
Business Development Business licensing Pilot production Marketing	$180,000
Total Expenses	**$1,440,000**

Reimbursement

As with any reimbursed procedures or services, the reimbursement of ProHAT will depend on coding, coverage, and payment. We can either create a new code with coding entities such as AMA, CMS, etc. or add onto existing codes such as HCPCS L5617 (addition to lower extremity, quick change self-aligning unit, above the knee or below the knee) or HCPCS L8680 (implantable neurostimulator electrode). Coverage will decide whether ProHAT services can be reimbursed, and the reimbursed cost will depend on payment. If we can successfully add onto existing HCPCS codes, the cost can be reimbursed through Medicare for users of age 65 or above.

Future Work

As we are still in the preliminary stages of research and development, there is a lot of scope for future work. Our future work can be classified into the following categories:

- **Product Development**
  We will complete the development and testing of our proof-of-concept, alpha, and beta prototypes. Key features of the process include:
  - **Sensor optimization**: Sensors besides touch, flex, and pressure sensors may be considered for the capture of relevant sensory stimuli. We will test various sensor placements, arrangement, and density to optimize the sensitivity of the system.
  - **Algorithm development**: We will write, implement, and optimize an algorithm that can extract meaningful information from the data collected by the sensors. The extracted information from the algorithm will be used to provide precise sensory feedback to the users.
  - **Verification & validation testing**: We will test the effectiveness and reliability of ProHAT in the lab. Some major features that will be tested include sensor stability, battery life, wireless data transfer reliability, biocompatibility, etc.
  - **Clinical testing**: We will partner with diabetes clinics and US Veterans Affairs to recruit veterans with lower limb amputations and diabetes and conduct clinical testing of our beta prototype.

- **IP & Regulatory Affairs**
  We plan to file a non-provisional patent by 2023. ProHAT will require regulatory approval for sale as a medical device, so we will initially file for FDA approval for operation in the US market. Once ProHAT is released into the US market, we will consider expansion to foreign markets after consultation with strategists and development of business plans compatible with the markets.

- **Funding**
  We will acquire $1.44 million in funding for initial operations by 2022. These funds will come from business competitions, accelerators, US Veterans Affairs R&D programs, etc.

- **Business Development**
  We will establish manufacturing channels to begin pilot production in 2023. We will partner with (1) insurance firms to establish technological exclusivity and (2) diabetes clinics and lower limb prostheses providers for market entry, marketing, and distribution.

Market Entry Strategy

As we are targeting patients with lower limb amputations due to diabetes within the US, we will work with clinics that offer services to diabetic patients. Partnerships with diabetes clinics will help us establish a relationship with physicians and patients and create a powerful marketing channel for our product. The partnership will also enable us to gain access to a patient pool for our clinical trials.

Furthermore, we will partner with lower limb prostheses providers for market entry and market our product as a low-cost accessory to the prostheses that these companies provide. Through the partnership, we will also be able to exploit the distribution channels that these companies have established for the distribution of our solution. Such a partnership with established providers will increase our market presence and create trust between our product and our consumers.

Lastly, we will work with insurance companies to establish technological exclusivity. Once exclusivity is established, we will be able to dominate the market share with a limited number of competitors in the future.

Through these strategies, we believe that we can successfully enter the market. Although we will begin within the US diabetes patient market, we believe that we will eventually be able to expand into overseas markets and extend marketing efforts to non-diabetes patients through utilizing usage data collected from the diabetes patient population to generate marketing material.

Summary

The prevalence of lower limb amputations is greatly heightened in individuals with diabetes. In the last few decades, growth in the number of individuals with lower-limb amputations has accompanied the growth in the number of individuals affected by diabetes, and this upward trend is expected to continue. Different types of lower limb prostheses are available in the market, but they fail to satisfy the needs of lower limb prostheses users with diabetes as they are expensive, lack sensory feedback, and neglect neuropathy. Despite research that suggests lack of sensory feedback in the lower limbs is associated with gait dysfunctions, imbalance, pain, and injuries, there are no solutions available in the market or in development that offer meaningful sensory feedback to lower limb prostheses users with diabetes.

ProHAT has a lot of benefits to offer. As a haptic accessory to already-fitted lower limb prostheses, it offers a cost-effective, versatile means through which users can retrieve somatosensory information from the prostheses. There are three significant innovations in our technology. The first is the integration of a user-friendly mobile app where the users can visualize the data from sensors and modulate the sensory feedback intensities. The second is the embedded sensors and electronics in our sensor system components, which offer great adaptability and flexibility for implementation at any location based on the users' preferences. The third is affordability. Users do not need to buy and fit new prostheses for sensory feedback; they can purchase and fit ProHAT for use with already-fitted prostheses. Through such innovations, ProHAT effectively addresses the needs of lower limb prostheses users with diabetes, enhances their clinical outcomes, and improves their quality of life.

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