

Rejuvagen

Providing personalized sleep health recommendations

Sarah Montgomery

1. Executive Summary

Rejuvagen's goal is to provide consumers with personalized sleep solutions based on their genetic background. Using a saliva sample, a panel of pre-selected sleep related genes and a proprietary algorithm, we will evaluate 4 domains of sleep health including: 1. Sleep duration, 2. Sleep quality, 3. Sleep patterns, and 4. Time-to-sleep. Based on research surveying candidate genes associated with these sleep domains, we aim to identify behavioural health changes that can be used to improve overall sleep health. Rejuvagen is currently in its idea phase; however, a candidate gene list is currently being prepared for development of an algorithm; it is expected that this list will be completed by December 2017. It is expected that the final product will be released to the market within three years.

2. Market Analysis

2.1. Problem

Many people struggle to get a good night's sleep and current solutions (ie. drug therapies) do not permanently resolve sleep problems; they merely provide a bandaid solution often accompanied by adverse side effects. Lack of sleep is associated with chronic diseases including type 2 diabetes, cardiovascular diseases, and cancer. Furthermore, sleep deprivation can impact cognitive processes (ie. attention, working memory, and judgment), affecting day-to-day activities.

2.2. Market Need

The customers will be individuals who struggle with insomnia or undiagnosed features of insomnia. Our target population includes full time working individuals between the ages of 25 and 65. Interestingly, Statistics Canada reported that full time working men got approximately 14 minutes less sleep than full time employed women. However, more women than men reported difficulty falling or staying asleep (35% versus 25%, respectively). US statistics are similar; in fact, the Centre for Disease Control reported that women experience more difficulty falling or staying asleep than men as well. Finally, Statistics Canada reported that individuals with an income greater than or equal to \$60 000/year were more likely to experience decreased total sleep than those who made less; this is important as it suggests that individuals who stand to benefit the most from this product are those that are most likely to be able to afford it.

2.3. Market Size

According to Persistence Market Research, it is estimated that the North American sleep aid market (including medications, supplements, and devices) in 2014 was worth US \$31.9 billion. Persistence Market Research further reported a compound annual growth rate of 5.7%, and a projected value of US \$44.5 billion by 2020 for the sleep aid market. Recently, Aviva published a health check report (2016) in which, Canada ranked third for least sleep, with 31% of Canadians reporting they do not get sufficient sleep. In the US, Consumer Reports found that 164 million Americans struggle to get adequate sleep at least once a week, and although US \$41 billion was spent on sleep therapies in 2015, many of these therapies were not effective in managing sleep problems. Based on these reports, our total Canadian market estimate of individuals reporting they do not get sufficient sleep is 11, 248, 784 (Canadian population: 36, 286, 400) and our total US market estimate is 164, 000, 000. We expect to capture 5% (562, 439) of the Canadian market and 10% (16, 400, 000) of the US market.

3. Competition

3.1. How are Customer Needs Addressed Today

Currently, medications, sleep monitoring devices, and lifestyle modifications (ie. dietary or physical activity changes) are used to manage insomnia. Lifestyle modifications are effective for some individuals; however, many people do not respond to these changes. Drug therapy is an effective therapy, although it remains a bandaid solution, and can present with adverse side effects including addiction to these medications. An alternative sleep health solution that has become increasingly popular is the use of sleep apps. The aim of these apps is to motivate individuals to take steps towards developing good sleep habits. Many apps have functions that allow individuals to track sleep using motion detector technology. However, the accuracy of motion detecting functions of sleep apps are controversial, with many experts agreeing they are not accurate.

3.2. Environmental Scan

The following companies offer either direct-to-consumer or health care provider-to-consumer genetic testing services related to nutrition, fitness, ancestry, disease risk, and traits: 23andMe, Gene by Gene, Nutrigenomix, Gene Planet, Ancestry, DNA Fit, DNA Testing Centres of Canada, xR and Athletigen. Athletigen is currently the

only company that profiles some sleep-related genes; however, the coverage of their sleep-related genes is narrow and their product is focused on sport performance genetics.

3.3. Competitive Advantage

Currently, most sleep therapies focus on managing symptoms. The advantage of our technology is that it aims to optimize an individual's sleep cycle (including total sleep time, sleep frequency, and sleep patterns) based on genetic information. Instead we aim to use a targeted approach to improving sleep problems rather than blindly targeting insomnia-related symptoms. Another advantage of this product is that there are no expected adverse biological side effects. The algorithm component sets it apart from many other genetic profiling services in that we do not simply profile genes and report genotype results to consumers; instead, we provide information and recommendations to consumers in a user-friendly manner.

4. Commercialization Plan

4.1. Science / Technology Overview

Consumers will provide a saliva sample for DNA extraction and genotyping. Genotyping results will be run through our proprietary sleep-regulatory genetic algorithm. The algorithm will generate a performance score for each of the following sleep parameters: 1. Sleep frequency, 2. Sleep duration, 3. Sleep intervals, and 4. Sleep timing based on gene governing these parameters. Personalized sleep health recommendations will be provided in a consumer-friendly report. A second product line will include a blood collection kit for DNA methylation and gene expression analyses to characterize functionality of the individual's genetic profile.

4.2. Growth Strategy

The proposed product is still in its infancy and no partnerships exist so far. At this stage, we still need to apply for IP; a patent will need to be registered in order to proceed with product development. Several key partnerships will be integral in the product development process. A strong scientific advisory board is important for providing expert opinion on the quality of scientific literature used in product development. A manufacturer will be needed for production of the DNA collection kit. Bioinformaticians and computer scientists will be needed for design and testing of the algorithm. Partnerships with industry groups, academic institutions, and hospitals interested in using this product for research purposes will be important for product growth and evaluation. Long term goals include: 1. expanding the product line to include gene expression and DNA methylation analyses to evaluate the consumer's , 2. developing an app that will allow consumers to integrate genomic results with lifestyle behaviour and phenotypic data (ie. sleep quality, frequency and subjective restfulness scores) to determine whether or not sleep health is improving in response to recommendations, 3. research and education activities/programs for the public.

4.3. Milestones

2017: Preliminary research and development

Sarah Montgomery and partnering scientists will conduct systematic literature reviews to establish a gene target list; this list will be used to create the algorithm. A literature review has been initiated and some candidate genes identified. All literature used for product development will be given a quality score to ensure adequate scientific rigor. This milestone will cost \$10, 000 and will be completed within 12 months.

2018: IP registration, product development, and third party lab identified and secured

A bioinformatician/computer scientist will be hired to design, build and test the algorithm that will be developed based on the gene target list. A manufacturer will be identified for production of a DNA collection prototype kit. A partnering lab that can provide genotyping services will be identified. A provisional IP for the algorithm will be registered in this year. This milestone will cost \$228, 000 and be completed within 12 months.

2019: Beta product testing (6-7 months). Approval of final product (5-6 months).

Beta testing consumers will be identified. The product will be provided free of charge in exchange for feedback on the product's usability and quality. Evaluation of the algorithm's performance will be conducted by a bioinformatics team. Concurrently, extensive advertising will be used to generate interest and demand prior to final product release. The final product will be approved by Dec 2019; it is expected this will cost \$405, 500.

2020: Product sent to market.

Feedback and quality assurance will be conducted for product improvement. Depending on customer volume, development of a custom DNA microarray (for enhanced efficiency) will be completed by March 2020. The microarray will be customized by Rejuvagen's scientific advisory team in collaboration with a microarray manufacturer. It is expected that this milestone will cost \$440, 500.

5. Financial Plan

5.1. Financial Needs and Justification (NB. All cost estimates presented in CAD)

2017 Pre-product development: *Contract service fees* (literature review) - \$10, 000, **Total: \$10, 000**

2018 Prototype development: *Business registration/incorporation fees* - \$10 000, *Employee salaries* - \$100 000 (1 bioinformatician or computer scientist), *Computer* (for algorithm design and analysis) - \$3 000, *Software* (for algorithm development): \$1 000, *DNA kit prototype + packaging materials* - \$500, *Packaging design service fees* - \$1 000, *Shipping fees* (for ordering kits and materials - \$1 000), *Web hosting fees* (company website) - \$10 000, *Office space* (office share) + *mailbox* - \$1 500, *Legal services* (related to provisional IP, privacy/protection, data storage/management, funding prospectus, etc) - \$100 000, **Total: \$228, 000**

2019 Beta product testing: *Saliva collection kits* - \$1 000 (50 kits), *DNA extraction/genotyping reagent fees* - \$6, 000, *Lab service fees* (DNA extraction and genotyping) - \$10 000 (\$25/hour x 50 samples x 8 hours), *Shipping fees* (for ordering kits/materials and shipping consumers' kits) - \$2, 000, *Employee salaries* (1 bioinformatician and 1 computer scientist) - \$200 000, *Office space* (office share) + *mailbox* - \$1 500, *Web hosting fees* (company website) - \$10 000, *Legal services* (related to filing IP, privacy/protection, data storage/management, etc) - \$175 000, **Total: \$405, 500**

2020 Final product and further product developments: *Marketing/advertising* - \$1 000, *Datastorage/management fees* - \$40, 000, *Sample storage/management fees* - \$50 000, *App development* (includes employee salaries and related service fees) - \$ 220, 000, *Data analyst/project coordinator salary* (for collecting, entering and analyzing genotyping results) - \$50, 000, *Office space* (office share) + *mailbox* - \$1 500, *Web hosting fees* (company website) - \$10 000, *Legal services* (related to privacy/protection, data storage/management, etc) - \$50 000, *Microarray prototype (including custom design, sample chip/kit, and testing service fees)* - \$18 000 (\$375/sample x 48 samples), **Total: \$440, 500**

5.2. Fundraising plan

Seed Funding: Gust, Women's Enterprise Centre (BC), and/or bank loans. Initially, Rejuvagen will apply for grant funding through the Women's Enterprise Centre and a bank loan to support its initial pre-product development groundwork. We will also fundraise through Gust's start up launch initiative; however, trading equity or services for support will likely be the most attainable option for funding at this stage.

Launch and Growth Funding: Quark Venture is a Canadian venture capital investment firm that recently developed a \$656 million biotechnology fund in partnership with China's GF Securities. Quark's investment portfolio is primarily focused on biotechnology and health science companies. Upon developing our prototype, we plan to seek out Quark and other venture capitalists/angel investors for product launch funding (Genesys is a Canadian venture capital firm investing in start-ups centered around biotechnology and/or health services and remains an ideal target venture capital opportunity).

5.3. Exit

Out-licensing: Although Rejuvagen is still in its pre-product development phase, the development of a formal protocol for out-licensing products to regions outside of Canada is important. The US and some European countries have genetic testing legislation protecting citizens from insurance company discrimination. With fewer privacy concerns, these countries represent ideal markets to penetrate. We expect a large proportion of our revenue to come from these regions and therefore, out-licensing will be invaluable in successfully entering these markets.

Mergers and Acquisitions (M&A): We view 23andme and other well established genomic start ups as ideal M&A opportunities. In the event that such an opportunity would benefit the company in the future, 23andme represents an ideal opportunity. Athletigen recognizes sleep health as a vital contribution to sport performance; therefore, Rejuvagen and Athletigen could both potentially benefit from an M&A opportunity.

5.4 Team

A scientific advisory board (SAB) will provide expertise on all areas of scientific inquiry relevant to research and development. Working with the SAB, the computer scientist and bioinformatician will be responsible for algorithm development and data management. A program assistant/manager will be hired for day-to-day tasks, and development of education materials/workshops. A financial advisor will be hired on a contract basis in order to establish and evaluate our financial plan. An accountant will be hired to manage business finances. A lawyer will be hired to handle all legal issues pertaining to development, commercialization and management of the product and related services. As the business grows, other experts will be hired to handle human resources, research and development, and marketing.