Innovative Solutions for Neurological Monitoring

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Executive Summary

Introduction

BioWires™ is developing a new solution to the existing problems of diagnosing the root cause of a seizure. Current methods for diagnosis use external electroencephalograms (EEGs), which are labor intensive, prone to error, and aesthetically unappealing. Our subdermal and wireless CROWN™ Series EEGs will provide high diagnostic accuracy while remaining cosmetically unobtrusive and will not require an expensive EEG technician.

Market Opportunity

The EEG is a valuable and proven tool used to diagnose and monitor multiple neurological disorders, including non-convulsive seizures, epilepsy, sleep disorders, migraines, brain tumors, and a number of psychological dysfunctions.

BioWires™ is targeting two market segments: the ambulatory EEG (aEEG) and ICU EEG market. Ambulatory EEGs are used to determine the root cause of a seizure, particularly to determine if that cause is epilepsy or not. This market is large: 1 in 10 Americans will experience a seizure in their lifetime.[1] Epilepsy currently affects more than three million people in the U.S. and over 200,000 new cases are diagnosed each year.[2] Facilities are also actively looking for ways to reduce costs. Moving from an in-hospital EEG to an aEEG relieves bed space and staffing shortages and provides a better diagnosis, because the patient is tested in their natural stressful environment. This shift is driving the high CAGR of the aEEG market: 7.4%.[3]

EEGs are also used in intensive care units to monitor head injury and post-surgery patients. Continuous EEGs (cEEGs) in the ICU can offer early detection of non-convulsive seizures and other related complications, which saves lives.[4] Due to high costs, EEGs are not yet common place in all ICUs. However, medical professionals, such as those in Duke University's ICU, said that if there were a better and less costly solution, they would use EEGs in all of their rooms. The CAGR of EEGs in the ICU nationally is also growing at an attractive rate: 15%.[5]

Current Solutions

Outpatient EEG monitoring, using an aEEG device, can prove to be 51-65% cheaper than inpatient monitoring.[6] In addition, outpatient monitoring allows for a natural environment and can be more comfortable for the patient. Current outpatient monitoring devices allow for a maximum of 72 hours of data collection, which forces the patient to visit the hospital daily. Electrodes from these devices are glued to the scalp and are connected to a control box, which the patient must carry around at all times. This process is unsightly and prone to error to shifting electrodes.

In the ICU, continuous EEGs are currently being used to monitor patients with traumatic brain injuries. They are subject to the deficiencies associated with aEEGs, and in addition, they cause clutter by reducing available "head real-estate". Expensive EEG technicians are required to apply and maintain

[1] Epilepsy Foundation. "Epilepsy and Seizure Statistics". <http://www.epilepsyfoundation.org/about/statistics.cfm>, accessed 20 March 2009.
[2] Epilepsy Foundation. "Epilepsy and Seizure Statistics". <http://www.epilepsyfoundation.org/about/statistics.cfm>, accessed 20 March 2009.
[3] Frost and Sullivan U.S. Patient Monitoring Industry Outlook: Long-term Epilepsy Monitoring Equipment Market A369-56 p. 267.
[4] Claassen, Jan and Stephan Mayer. "Continuous Electroencephalographic Monitoring in Neurocritical Care". Current Neurology and Neuroscience Reports. 2002.
[5] Sage Sourcebook of Modern Biomedical Devices 2007. <http://books.google.com/books?id=KYt2x-soi3YC>, page 1160.
[6] "Ambulatory EEG". <http://emedicine.medscape.com/article/1139483-overview>, accessed 3 March 2009.

electrodes, which often shift and fall off. These technicians are not available at all times in the day, which is a problem when patients need to have a cEEG test.

The dominant players in the EEG market are Cardinal Health, Natus Medical and Nihon Kohden. Across the competition, however, no one has a product to address the key flaws of scapular electrode based EEG.

Our Solution

BioWires™ is developing two wireless and subdermal EEGs: CROWN1™ is designed for the ambulatory market and the CROWN2™ for the ICU market. Our device is comprised of four needle-width electrode strips which are implanted underneath the scalp. It is virtually invisible to the outside observer. Our device increases measurement accuracy, improves patient comfort, and reduces long-term facility costs because it requires minimal maintenance. This cosmetically unobtrusive device allows the patient to have more mobility and an increased quality of life, while meeting their clinical needs for a proper diagnosis.

Our product addresses both mid and long-term clinical needs for EEGs. In contrast to current EEG devices, our device can be implanted easily and does not need an expensive EEG technician to reattach external electrodes. Our longer-term internal data collection system creates less stress for the patient, because long stays and frequent revisits to the hospital are not required. This also cuts costs for hospitals and insurance companies, creating benefits for these key stakeholders.

Technology and Intellectual Property

Based on research of prior art, we have a strong IP position, especially considering the implantable and wireless nature of our product. *Details provided in* ***Product and Service*** *section of our business plan.*

Business Model and Success Metrics

Our product will be sold on a *per-case* basis, which is notably different from our competitors who charge a one-time large upfront cost, making our CROWN™ Series EEGs attractive to less wealthy facilities. High cost is one of the largest hindrances to higher EEG adoption in the aEEG and ICU market segments. We are requesting two rounds of funding: $3 million in seed round funding and $13 million in Series A funding. After a liquidity event in the seventh year, the investor can expect a 40.1% IRR.

Exit Strategy

In the long-run, especially considering our strong IP position, our product would bring an increased market share to a bigger player. We would be a profitable and synergistic acquisition for one of the larger market players. Current investment in our product establishes a competitive edge in a rapidly growing market, with a substantial possibility for increased profit through expansion devices using our wireless electrode technology. BioWires™ is developing a full product line, which would be an additional benefit for an acquiring company.

Our Team

The inventor of our ambulatory EEG subdermal device is Thomas Jochum, a Duke University Biomedical Engineering PhD Candidate and a renowned engineer whose chips are used in millions of computers worldwide. Our project leader is Chris Hansen, a Duke University MEM Candidate. Undergraduate Duke University members include David Chen, Andrea Coravos, Brian Kim, and Nick Sarnoff. Our team looks forward to helping BioWires™ expand, and we have budgeted in our plan for an experienced CEO and CFO to take us to the next stage.