

**EXECUTIVE SUMMARY**

Signal Advance (SIGNAL ADVANCE) has developed and filed patents for a system for advancing the detection of electrical signals from medical devices to accelerate the timing of their response to medical events. First Principals, Inc. (FPI) has been engaged to provide an approximate valuation for the subject Intellectual Property.

In this document, FPI will establish the estimated current value of:

- US Patent Application “Utility and Method for the Application of Negative Group Delay (NGD) Bandpass Amplification to Analog Waveform Signal Detection, Acquisition and Processing for the Purpose of Control, Reinforcement, Intervention, Amelioration, Enhancement, Suppression of Processes Underlying the Detected Signal.”

[Issued Patent (US 8,452,544): “Utility and Method for the Application of Signal Advance Amplification to Analog Waveform or Signal Detection, Acquisition and Processing”]

Technology: The technology represents a significant advance in the ability to react quickly to biomedical electrical signals, enabling more rapid intervention than is currently possible. There appear to be no competing technologies at this time.

Intellectual Property: SIGNAL ADVANCE’s patent application represents a new and unique application of the concept of “signal advance” to medical applications. The patent is seminal in concept. No other patents were discovered that prevent SIGNAL ADVANCE from practicing its technology, or that offer superior solutions to the issues addressed by SIGNAL ADVANCE.

Market: The *addressable* market for SIGNAL ADVANCE totals approximately \$3 billion in 20 years time, to be penetrated to levels of ~4% with slow initial impact. SIGNAL ADVANCE will compete based on superior technology and performance, across a range of products.

VALUE: Including the projected, risk-adjusted licensing royalties, we project A NET PRESENT VALUE OF UP TO ~\$10.4 MILLION. This valuation will increase rapidly as the technology is proven and then successfully applied to products in this very large market.

Markets projected in the above scenarios are highly speculative. These markets are unproven, as the technology is only recently being introduced. Valuations are intended for planning purposes only.

N.B. THE ABOVE VALUATION IS ONLY AN ESTIMATE WITH NO GUARANTEES OF FUTURE OUTCOME. IT IS, HOWEVER, DELIBERATELY CONSERVATIVE. WE HAVE INCLUDED ONLY THOSE MARKET SECTORS FOR WHICH RELIABLE DATA CAN BE CITED. WE HAVE USED CONSERVATIVE ESTIMATES OF MARKET SHARE AND OF MARKET GROWTH RATES. THERE MAY BE A NUMBER OF OTHER MARKET SEGMENTS ACCESSIBLE BY THE SUBJECT PATENTS, AS NOTED IN THE TEXT. THEIR ADDITION WOULD ADD TO THE STATED VALUE. THUS, WE REGARD THE ABOVE VALUE AS A CONSERVATIVE VALUE FOR THE PATENT(S)

The significant element of this concept is the ability to temporally advance electrophysiological waveforms potentially resulting in earlier or more rapid detection of anomalous activity which may facilitate more effective and potentially proactive ameliorative intervention.

Key SIGNAL ADVANCE Technology Features

The SIGNAL ADVANCE system offers the unique feature or:

- The ability to advance the detection of electrical signals in real time

Key SIGNAL ADVANCE Technology Benefits

SIGNAL ADVANCE technology provides a significantly superior Tee Box experience:

- The ability to detect the onset of anomalous ECG and other medically important waveforms at an earlier time than currently possible
- The ability to use this information for earlier intervention in medically harmful situations.

The system can be deployed in

- Cardiology (pacemakers, defibrillators, etc.)
- Neurology (epilepsy, pain management, etc.)

State of Development of the Technology

The technology covered by the subject patents is in the development process. SIGNAL ADVANCE has developed several product concepts based on the technology as described above.

Competing Technologies

Current competition arises from standard methods of detecting and processing medically significant electrical signals in cardiology and neurology. It is accepted in medical practice that rapid response is valuable, but current devices rely on delayed signal detection characteristic of current technology.

SUMMARY:

The technology represents a significant advance in the ability to react quickly to biomedical electrical signals, enabling more rapid intervention than is currently possible. There appear to be no competing technologies at this time.

**INTELLECTUAL PROPERTY OVERVIEW**

The technologies on which the SIGNAL ADVANCE products are based are subject to the following US Patents:

- US Patent Application “Utility and Method for the Application of Negative Group Delay (NGD) Bandpass Amplification to Analog Waveform Signal Detection, Acquisition and Processing for the Purpose of Control, Reinforcement, Intervention, Amelioration, Enhancement, Suppression of Processes Underlying the Detected Signal” [Issued Patent (US 8,452,544): “Utility and Method for the Application of Signal Advance Amplification to Analog Waveform or Signal Detection, Acquisition and Processing”]

The patent application represents a new technique whereby a signal from a medical device (e.g. a pacemaker or defibrillator) could be detected at an earlier stage, enabling intervention more quickly. The patent is invented by Chris Hymel.

*Key Features of the SIGNAL ADVANCE IP*

The innovation represents

- The ability to detect the onset of anomalous ECG and other medically important waveforms at an earlier time than currently possible
- The ability to use this information for earlier intervention in medically harmful situations.

*Competing Patents*

First of all, there were no patents found that linked the concept of “signal advance” to applications in cardiovascular or neurostimulation applications. Most of the patents in the search reflect various aspects of the intersection of electronics and medical devices. They included various concepts in prevention of tachycardia in particular.

Other searches performed included combinations of classification and term searches, for instance. These and other techniques retrieved lists of literally hundreds of patents in the general area of cardiology.

When the specifically-claimed aspect of the present innovation was searched, the following patents were identified:

- **US Patent 7,277,750** “Method and apparatus for anti-tachycardia pacing and defibrillation” describes in particular the need for more rapid signal detection and response in treating tachycardia.
- **US Patent 7,171,268** “Implantable cardiac stimulation device providing accelerated defibrillation delivery and method” describes a method of accelerating delivery of defibrillation signals from an implanted medical device to the heart.

Other patents were identified which deal with other aspects of implantable medical devices, but none cite the use of “signal advance” techniques to achieve their goals.

*Summary*

SIGNAL ADVANCE’s patent application represents a new and unique application of the concept of “signal advance” to medical applications. The patent is seminal in concept. No other patents were discovered that prevent SIGNAL ADVANCE from practicing its technology, or that offer superior solutions to the issues addressed by SIGNAL ADVANCE.

**PRODUCT AND MARKET OPPORTUNITIES***Implantable Medical Devices Market*

The SIGNAL ADVANCE system can be applied to

- Implantable cardiovascular devices
  - Pacemakers
  - Defibrillators
  - Anti-tachyarrhythmia devices
- Implantable neurostimulator devices
  - Pain control
  - Epileptic therapy

*The Implantable Medical Devices (IMD) Market:*

In 2004, there were approximately 2.4 million patients with pacemakers and 460 thousand with ICD's, these numbers are expected to increase at annual rate of 5% and 14-22%, respectively. The earliest pacemakers stimulated at a constant rate, so did not adjust for varying physiological demands or normal, organic activation, potentially stimulating during a naturally occurring T-wave thus potentially causing tachycardia or fibrillation. The use of integrated circuits to sense atrial/ventricular signals and programmable functionality in "demand" type pacemakers and later improvements including the use of microprocessors, allowed for dual-lead placement, sensing and stimulation. More recent advances resulted in the development of cardiac resynchronization therapy (CRT), implantable cardioverter defibrillators (ICD), improved rate-response (adaptive) pacing algorithms, as well as, a number of other improvements which have enhanced electro-physiologically-relevant pacing. Recent investigations have focused on the application of cardiac pacing technology the management of atrial fibrillation. While the pacing technology has improved significantly, the current sensing technology must still detect at least two consecutive heartbeats to determine the current heart rate (more to be more accurate) and then execute a necessarily delayed response. However, atrial anti-tachycardia therapies are most effective the earlier the delivery following onset.

With the application of "Signal Advance" amplification may be possible to "pre-" detect a heart beat determine its rate relative to the previous detection and deliver an appropriate stimulation response during that same beat. Further, this response could potentially suppress an anomalous electro-cardiac signal and by exploiting constructive interference. According to industry resources, the US medical implant industry currently generates some \$23 billion annually. This includes microelectronics, specialty metals, polymers, elastomers, biologicals and pharmaceuticals, ceramics) and type (e.g., cardiac, orthopedic, breast, ophthalmic, neurological, drug, urological, cochlear, dermal/tissue).

Analysts estimate the worldwide CRM (Cardiac Rhythm Management) market, comprised of pacemakers and implantable defibrillators, exceeded \$8 billion in 2005 and is estimated to be ~\$11 billion in 2007. Medtronic, Johnson & Johnson, Guidant, Boston Scientific, Stryker, Zimmer, St. Jude Medical, Biomet, Smith & Nephew, and WL Gore are some of the more significant players.

*Additional Market Opportunities*

In addition to applications in Cardiac care, the "signal advance" technology will have impact on neurology through neurostimulator devices. However, these applications are sufficiently far in the future, and will require such significant development, that their contribution will be small. In the valuation calculation ..., the distant future timeframe multiplied by very high risk factor reductions, render the value of future revenues discounted to present value to be very small.

Competition

Further challenging SIGNAL ADVANCE's overall sales will be competition from current technology and the step-wise advances it will achieve in the next decade or so. SIGNAL ADVANCE's impact will be as an add-on to these existing technologies in enhancing their future value.

Market Available to SIGNAL ADVANCE:

SIGNAL ADVANCE's technology will likely be suitable for only a fraction of the products sold into the above applications. We see the immediate benefit of SIGNAL ADVANCE in Anti-tachycardia applications, and eventually in treating epilepsy. In other applications, the impact is likely to be smaller.

*Cardio:* if ~20% of cardio IMDs are used for the treatment of anti-tachycardia, and if the contribution of SIGNAL ADVANCE to the success of products in this segment is ~10%, then SIGNAL ADVANCE could expect to earn some 2% = 20% X 10% of that \$11 billion market.

*Neuro:* The worldwide market for implantable neurostimulation devices holds much promise for patients, physicians, device OEMs and investors. While still considered to be in an infant stage the commonly held opinion of venture capitalists, equity analysts and most device companies is that the neurostimulation device market could eventually exceed the market for implantable cardiac rhythm management devices, currently a darling of the medtech sector at \$11 billion in revenue. If we estimate that this market will reach such a stage in 15 years or so, we can project some contribution from neurostimulation in to the calculation of present value. Again, SIGNAL ADVANCE would participate in the revenue generated at a level of ~2% or less.

We estimate the current growth rate of Cardio applications to be ~18%, tapering slowly to ~5% in 15 years. We estimate the growth rate of Neuro applications to explode in 5 years to 25%, tapering to ~15% in 15 years.

SIGNAL ADVANCE' penetration into these applications would be 100%, as SA has no current competition.

Summary

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