SIGNALIFE, INC.
Form 10KSB
April 02, 2007

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 10 KSB

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S Annual Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2006

£ Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____
Commission file number: _____

SIGNALIFE, INC.

(Name of small business issuer in its charter)

Delaware	**87-0441351**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

531 South Main Street, Suite 301
Greenville, South Carolina 29601
(864) 233-2300

(Address of principal executive offices) (Zip code)
(Registrant s telephone number)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Common Stock, Par Value $0.001	**American Stock Exchange**
(Title of each class)	(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(g) of the Exchange Act: £

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days: Yes S No £

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained in this form, and no disclosure will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB: £

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): £

The issuer s revenues for its most recent fiscal year (fiscal 2006) were $190,170.

The aggregate market value of the issuer s voting and non-voting common equity held by the issuer s non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days, was: $31,875,271 as of March 27, 2007.

The number of shares outstanding of each of the issuer s classes of stock as of as of March 27, 2007, the latest practicable date, was 44,945,855 shares of common stock (voting common equity) and 97,909 shares of series A convertible preferred stock (voting preferred equity), excluding accrued but unissued dividends

Documents Incorporated By Reference

The issuer has not incorporated by reference into this annual report: (1) any annual report to the issuer s securities holders, (2) any proxy or information statement, or (3) any prospectus filed pursuant to Rule 424(b) or (c) of the Securities Act.

Transitional small business disclosure format (check one): Yes £ No S

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ADVISEMENTS

The information set forth in the section of this annual report captioned *Business* is current as of March 27, 2007, unless an earlier or later date is indicated in that section. The information set forth in the sections of this annual report other than *Business* is current as of December 31, 2006, unless an earlier or later date is indicated in those sections.

We sometime refer to our common stock, par value $0.001 per share, our blank check preferred stock, par value $.001 per share, and our designated series A convertible preferred stock, par value $0.001 per share, in this annual report as our *common shares*, *preferred shares*, and *series A preferred shares*, respectively.

On April 11, 2003, we effected a split in our common shares on a 3:1 forward basis through the mechanism of a stock dividend. Whenever we make any reference in this annual report to the grant or issuance of common shares or options or warrants to purchase common shares, such reference shall, for comparison purposes, be made in reference to post-split numbers and, in the case of options and warrants, post-split exercise prices, unless we state otherwise.

In this annual report we make a number of statements, referred to as *forward-looking statements*, which are intended to convey our expectations or predictions regarding the occurrence of possible future events or the existence of trends and factors that may impact our future plans and operating results. These forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to us and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe to be appropriate in the circumstances. You can generally identify forward-looking statements through words and phrases such as *seek*, *anticipate*, *believe*, *estimate*, *expect* *intend*, *plan*, *budget*, *project*, *may be*, *may continue*, *may likely result*, and similar expressions. When reac forward looking statement you should remain mindful that actual results or developments may vary substantially from those expected as expressed in or implied by that statement for a number of reasons or factors, such as those relating to: (1) whether or not a market for our various heart monitoring devices and services develops and physicians, patients, insurance companies and government and other third-party reimbursement agents accept those products and services and, if a market develops, the pace at which it develops; (2) our ability to successfully sell our various heart monitoring devices and services to the extent a market develops; (3) our ability to attract the qualified personnel to implement our growth strategies; (4) our ability to develop sales, marketing and distribution capabilities for our biomedical devices and services, either internally or through outside contractors or partners; (5) the success of our research and development activities in developing additional heart monitoring devices and other biomedical devices using our proprietary technologies, and our ability to obtain federal or state regulatory approvals governing those biomedical products and services; (6) the accuracy of our estimates and projections; (7) our ability to fund our short-term and long-term financing needs; (8) changes in our business plan and corporate strategies; and (9) other risks and uncertainties discussed in greater detail in the sections of this annual report, including those captioned *Management s Discussion And Analysis Of Financial Condition And Results Of Operations* and *Uncertainties And Risk Factors That May Affect Our Future Results And Financial Condition*.

Each forward-looking statement should be read in context with, and with an understanding of, the various other disclosures concerning our company and our business made elsewhere in this annual report as well as other public reports we file with the United States Securities and Exchange Commission (the *SEC*), including any amendments to this annual report. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statement contained in this report to reflect new events or circumstances unless and to the extent required by applicable law.

BUSINESS

Overview

Signalife, Inc. (*Signalife* , *we*, *us*, *our* and similar terms) is a medical device company focused on researching, developing and marketing medical devices which monitor and measure physiological signals in order to detect diseases that impact an individual s health. Physiological signals are small bioelectrical signals generated by the body. Our initial product is a patient module used as part of a heart monitor system to acquire, amplify and process physiological signals associated with an patient s cardiovascular system. Heart monitor systems are used, among other things, by heart specialists known as cardiologists to collect physiological data for electrocardiogram or ECG tests for the purpose of detecting and identifying cardiovascular disease. Our patient module operates using a proprietary and patented amplification technology which provides the capability to enlarge and process the physiological signals to discriminate them from ambient or background electromagnetic noise and to facilitate the examination of the signal data for diagnostic purposes.

Our corporate offices are located at 531 South Main Street, Suite 301, Greenville, South Carolina 29601. Our telephone number is (864) 233-2300.

Our common shares are currently quoted on the American Stock Exchange or AMEX under the symbol SGN.

Recent Corporate History

Signalife was originally incorporated in Delaware on January 19, 1987 under the name Mt. Olympus Enterprises Inc. Since our formation, we changed our name to Recom Managed Systems, Inc. on November 6, 1998, and then to Signalife, Inc. on November 2, 2005.

Prior to September 19, 2002, we were an inactive corporate shell. On September 19, 2002, we acquired certain know how, trade secrets and other proprietary intellectual property rights relating to the development of a physiological signal amplification equipment and technology, referred to in this annual report as the *Signal Technologies* , from ARC Finance Group, LLC (*ARC Finance Group*), our parent corporation, in exchange for 23,400,000 common shares (7,800,000 shares pre-split). The shares represented approximately 85% of our issued and outstanding common shares. We valued the Signal Technologies at $78,023 for financial accounting purposes, reflecting ARC Finance Group s cost to acquire the Signal Technologies from Dr. Budimir S. Drakulic as discussed below. The terms of the acquisition were determined by the parties on an arms-length negotiated basis. No independent valuation was sought from a business/technology appraiser or other third party due to financial constraints. There was no relationship between Signalife, including our officers, directors and shareholders, and ARC Finance Group, including its officers, directors and shareholders, prior to our acquisition of the Signal Technologies from ARC Finance Group. No finder s fees or other forms of consideration were paid by Signalife or ARC Finance Group or our respective officers, directors or shareholders in connection with our acquisition of the Signal Technologies.

The principal component of the Signal Technologies is a patented amplification technology which was originally invented by our Chief Technology Officer, Dr. Budimir S. Drakulic. The underlying patent covers methods of discriminating different biomedical signals from ambient electromagnetic noise. Also included in the Signal Technologies was an assignment of a license agreement dated December 9, 1993 between Dr. Drakulic and Teledyne Electronic Technologies (*Teledyne*) pursuant to which Dr. Drakulic granted a limited license to that company to

manufacture electroencephalogram or EEG monitor products based upon an early version of the amplification technology. This early version amplifier is also currently used by the National Institute of Health as well as companies such as Titan Systems and Teledyne, Inc. for purposes of monitoring different physiological signals. This license agreement specified that Dr. Drakulic retained ownership of the original patent and underlying technology and the

right to use technology to develop new products as long as they would not infringe on Teledyne s licensed products. Dr. Drakulic has since received a letter from Teledyne acknowledging that the use of the technology for our proposed heart monitor systems does not infringe on Teledyne s licensed products. Concurrent with our acquisition of the Signal Technologies, we obtained Dr. Drakulic s services as our Chief Technology Officer to lead our product development efforts.

ARC Finance Group is a Delaware limited liability company formed in May 2002 which is owned and controlled by Ms. Tracey Hampton. In or about May 2002, ARC Finance Group entered into an understanding with Dr. Drakulic pursuant to which it would fund informal proof-of-concept activities and product development costs to be incurred by Dr. Drakulic in order to establish to the satisfaction of ARC Finance Group the potential of the Signal Technologies for ECG applications, and would also pay other expenses of Dr. Drakulic, in exchange for the rights to acquire and market the Signal Technologies. Pursuant to that understanding, ARC Finance Group funded these activities and costs in the amount of $78,023 during the summer of 2002, and acquired the Signal Technologies from Dr. Drakulic when it became satisfied that the Signal Technologies could be applied for ECG applications. Following its acquisition of the Signal Technologies, ARC Finance Group sought a third-party company to license or acquire the Signal Technologies for its commercial development, leading to our acquisition of the Signal Technologies from ARC Finance Group. Since that acquisition, ARC Finance Group has remained a holding company for an investment in our company. ARC Finance Group s only investments and sources of revenue and business activity to date relates to Signalife. There is no past or current relationship between ARC Finance Group and Titan Systems or Teledyne Inc.

Description Of Heart Monitor Systems And ECGs

A heart monitor system is a system used to monitor and record changes in physiological signals associated with a patient s cardiovascular system. Heart monitor systems are used by heart specialists known as cardiologists to collect physiological data for electrocardiogram or ECG tests for the purpose of detecting and identifying cardiovascular disease. An ECG gives the cardiologist important information about the heart. For example, by examining changes in waveforms from 0.67 Hz to 40 Hz frequency range, a cardiologist can identify irregularities in the heart s rate and rhythm, known as arrhythmia. By examining changes in waveforms in the broader 0.05 Hz to 150 Hz frequency range, a cardiologist can identify different types of heart disease, including damage to the heart muscles or tissue resulting from (1) decreased blood flow attributable to the narrowing of the arteries, known as cardiac ischemia, (2) enlargement of the heart resulting from additional effort attributable to the hardening of the heart muscle, known as hypertrophy, and (3) the existence of past or presently occurring heart attacks.

When an ECG test is ordinarily conducted in a clinical setting, the physiological signals from the patient s heart are displayed through a heart monitor system called a 12-lead ECG, based on acquiring a signal from ten electrodes, one of which is attached to each of the patient s arms, six to the chest and one to each leg. The placement of the ten electrodes enables the heart to be examined for different diseases. Physiological signals generated by the heart are amplified and recorded in the form of a series of waveforms that can be displayed on a screen or printed on paper for interpretation by a cardiologist. Any irregularity in heart rhythm, damage or stress to the heart muscle will result in a deviation from a normal waveform.

There are three settings under which ECGs are normally taken: (1) the clinical or resting setting where the patient is immobile; (2) the ambulatory setting where the patient is mobile; and (3) the exercise setting where the patient is subjected to physical stress in a controlled environment. These three types of ECG tests are more fully described as follows:

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ECGs administered in the clinical or resting setting are generally taken (1) on an annual basis for older patients as part of their annual physical examination; (2) under emergency or exigent circumstances when an individual complains of symptoms typically associated with heart disease such as chest pains, shortness of breath or heart palpitations; or (3) as part of surgeries and medical

procedures, such as heart surgery. Most clinical ECGs are obtained in the resting setting. In a resting setting, the principal technical issue in interpreting ECG waveforms arise from the existence of ambient or background noise emanating from other electromagnetic sources, including (1) signals generated by the other organs, muscles and systems of the body, whether from movement or the performance by those organs of their bodily functions, and (2) signals generated by sources external to the body, such as electronic equipment, lights or engines. This ambient noise is commonly referred to as an artifact . As previously discussed, cardiologists can identify irregularities in the heart s rate and rhythm, known as arrhythmia, by examining changes in the 0.67 to 40 Hz frequency range. Because of the relatively large amplitudes of these waveforms in this range, cardiologists can, as a practical matter, easily identify arrhythmia notwithstanding the existence of electromagnetic ambient noise from other sources. However, it is very difficult for cardiologists to distinguish physiological signals from ambient noise in the broader frequency ranges used to identify different types of heart disease, including cardiac ischemia, hypertrophy and the existence of past or presently occurring heart attacks. The reason for this difficulty is that the physiological signals associated with these other heart diseases are of a much lower amplitude or strength in the lower 0.05 to 0.67 Hz and upper 40 to 150 Hz portions of the frequency range, meaning that they do not stand-out from the ambient noise in these portions and therefore cannot be easily discriminated from that ambient noise. In order to minimize ambient noise in the clinical setting, ECGs are normally taken in the hospital or physician offices. Cardiologists instruct the patient to lie in the supine position, being as still as possible while a reading is taken to reduce ambient noise caused by physical movement. Another method to reduce ambient noise is to reduce the sensitivity of the monitoring equipment, although this alternative results in a loss of signal quality and the ability to read certain signal intricacies.

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ECGs administered in the ambulatory setting are given in an attempt to identify so-called transient heart disease that is, problems that come and go, and that are not apparent when a standard clinical or resting ECG is performed. Examples of transient heart disease are cardiac ischemia and cardiac hypertrophy. Additionally, the existence of past or presently occurring heart attacks can escape detection without longer-term monitoring in a physically active or stressful setting. An ambulatory heart monitor system, commonly known as a Holter monitor, allows the patient s heart to be continuously monitored over a period of hours or days, while the patient carries out his or her daily activities under typical conditions of stress away from the physicians office or hospital. The principal technical limitation in deciphering ECG waveforms in an ambulatory setting is that in many cases, ambulatory heart monitor systems are unable to accurately identify many of the heart conditions they are intended to identify due to their inability to clearly distinguish and discriminate the physiological signals associated with these conditions from electromagnetic ambient noise in the lower and upper portions of the full 0.05 to 150 Hz frequency range. Therefore, the industry standard for ambulatory recorders is 0.67 to 40 Hz.

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ECGs administered in the exercise or stress setting are given while the patient exercises on a treadmill, step machine or exercise cycle to enable the cardiologist to monitor, among other things, the patient s heart behavior under conditions of physical stress. Exercise can exacerbate cardiovascular abnormalities that are not present at rest and it can be used to determine the adequacy of cardiac function. Similar to an ambulatory ECG, this allows the cardiologist to identify different heart disease such as cardiac ischemia and cardiac hypertrophy as well as the existence of past or presently occurring heart attacks that may not be evident under a clinical resting or simple ambulatory ECG test conditions. Indeed, many physicians administer a stress ECG before proceeding to an ambulatory ECG. While external sources of ambient noise can be reduced in the clinical setting when exercise ECGs are conducted, high levels of physical activity inherent in exercise ECGs generate higher internal levels of ambient noise due to necessary patient movement. To address this issue, exercise ECG devices are connected to computers which run sophisticated software

to filter and process physiological signals and produce average waveforms for interpretation by the cardiologist. However, the American Heart Association and American College of Cardiology each state that computer processing is not completely reliable

because of software limitations in handling noise, the technical limitations of the software algorithms and therefore, cardiologists are advised to look at the raw data and not rely solely upon the results obtained by software processing of original data.

Description Of Current Products

The core component of our heart monitoring systems is our battery-operated, digital 12-lead Model 100 Module, a compact device approximately 4 x 3.5 x 1.5 inches in size and 5.5 oz. in weight, that allows a patient s heart to be continuously monitored over a period of 24 to 48 hours in a variety of settings both non-ambulatory (stationary) and ambulatory (moving) such as hospitals, surgeries, clinics, doctors offices, exercise and sports medicine clinics and laboratories. The Model 100 Module contains both our proprietary patented amplification technology which acquires, processes and amplifies ECG signals, as well as Bluetooth technology which allows the acquired signals to be wirelessly transmitted to a personal computer for interpretation and storage by the physician.

The production version of our Model 100 Module was originally designed, engineered, fabricated and tested by Battelle Memorial Institute, Health and Life Sciences, pursuant to a research and development services agreement completed by Battelle Memorial Institute in December 2004. Battelle Memorial Institute is a global science and technology enterprise that designs, develops and commercializes technology and manages laboratories for customers. The pre-production model of our Model 100 Module, which was completed by Battelle Memorial Institute in December 2004, was tested and determined to comply with all applicable performance, safety, environmental and regulatory standards, including the United States Food And Drug Administration (*FDA*)-recognized consensual American National Standards Institute/Association for the Advancement Of Medical Instrumentation (*ANSI/AAMI*) EC-38 industry standards for ambulatory ECG devices, Federal Communications Commission (*FCC*) requirements for Human Exposure to Radiofrequency (RF), the FDA-recognized consensual industry standards for electromagnetic compatibility for medical devices (EMC), the FDA-recognized IE 60601-1 international safety standard relating to medical electrical equipment, and the FDA's Quality System Regulations. These testing results also satisfied our obligation under our abbreviated 510(k) submission to have supporting data in our files before marketing the Model 100 Module as part of the Model 100 Monitor System. The Model 100 Module also complies with ANSI/AAMI EC-11 and EC-13 ECG standards to the extent they relate to non-diagnostic features and alarm functions for stationary (non-ambulatory) ECG devices.

Fidelity 100 Monitor System

We are currently marketing our first heart monitoring system using our Model 100 Module the Fidelity 100 Monitor System. This system is an integrated system in which our Model 100 Module collects, processes and amplifies ECG signals from that patient through a set of twelve electrode lead sets provided with the system, and then wirelessly transmits that signal to a nearby personal computer provided with the system. The signals are then displayed on a computer monitor and can be printed on a printer provided with the system for analysis by the cardiologist.

We principally intend to sell the Fidelity 100 Monitor System as an integrated system containing all of the components the Model 100 Module, electrode lead sets, and a personal computer with monitor and printer, which could either be in a desk top or laptop configuration.

The Fidelity 100 Monitor System will be principally used for clinical (resting) and in-patient ambulatory applications. For example, ECG data may be instantaneously acquired, processed, amplified and transmitted to the personal computer for analysis in stationary settings, such as while conducting ECG tests in resting or in-patient ambulatory

settings or during surgeries.

Since the completion of our first production proto-types of the Model 100 Module in December 2004 as discussed above, we have conducted and as of the end of fiscal 2005 completed user preferences studies

to identify performance, usability and aesthetic aspects of our module and to select the various ancillary equipment to be used as part of the system, while finishing development of our proprietary ECG signal printing software and arranging contract manufacturing sources. Upon commencement of contract manufacturing activities in December 2005, we placed later-generation models to several cardiologists, hospitals, clinics and research institutions who expressed an interest in using and testing our system with the ultimate objective of purchasing the product. We formally initiated marketing of the Fidelity 100 Monitor System by presenting the system at the annual meeting of the American College of Cardiology held at Atlanta, Georgia, from March 12-14, 2006, and received our first orders for this product in October 2006.

Holter Monitor

The Model 100 Module was originally created as an ambulatory Holter device (the *Signalife Holter Monitor*), pursuant to which ECG data relating to arrhythmia and other transient heart disease is acquired, processed, amplified and stored in a computer storage chip contained in the Model 100 Module over a period of 24 to 48 hours while the patient carries out his or her daily activities away from the physicians office or hospital. The signal data can be either stored on a storage chip contained in the device and downloaded by the physician at a later date when the patient returns to the physician s office, or transmitted to a patient monitoring center that will forward the data or otherwise make it available to the physician over the Internet. We have already received FDA 510(k) clearance for this product. While a commercial version of the Signalife Holter Monitor is essentially completed, we are still evaluating which third-party software we will use with this product to scan the processed data. We have extended a right of first negotiation to an industry partner to distribute the Signalife Holter Monitor, and for this purpose are presently arranging evaluative tests of the Signalife Holter Monitor through a nationally-known research hospital, and will not commence marketing the product until the completion of these tests and negotiations. We anticipate that we will commence marketing the Signalife Holter Monitor by the end of fiscal 2007.

Description Of Products In Development Or Investigative Stage

Fidelity 200 Event Recording System

We have completed a pre-production version and successfully tested a non-prescription over-the-counter event recording system (the *Signalife Fidelity 200 Event Recording System*), and are currently designing, engineering and fabricating a production version of this product. This product incorporates our proprietary physiological signal acquisition and amplification technology to the non-prescription over-the-counter market.

The Signalife Fidelity 200 Event Recording System is a credit-card sized single-lead heart monitoring device which can be used as a non-prescription early-detection device by patients who desire to independently monitor their condition by recording and transmitting an ECG signal to a 24-hour monitoring center via a telephone phone line. At the onset of an event that will be recorded, a patient holds the event recorder to his/her chest, presses the record button, and records up to a 45-second event. The event recorder will be capable of storing up to six, 45-second recordings before transmission must take place. To evaluate recorded data, the patient calls the monitoring center and upon verbal communication with receiving station personnel, positions the monitor over the telephone mouthpiece, and starts the transmission by pressing the play button. Data is then transmitted to the monitoring center and can be immediately evaluated by a qualified ECG technician, cardiac nurse or cardiologist.

We anticipate that this product would be sold to consumers through retail outlets such as drug stores, retail pharmacies, and major retail discount chains. We plan on applying for FDA 510(k) clearance for this product as a

class II medical device in the second quarter of fiscal 2007. We anticipate that the production version will be completed, FDA clearance or approval received, and that we will commence marketing this product by the end of fiscal 2007. We are currently in preliminary negotiations with an

industry partner relative to the distribution of the Signalife Fidelity 200 Event Recording System, and also investigating monitoring centers.

Cardiac Vest

In conjunction with the Champ Car World Series, the North America-based formula-one style auto racing circuit, we have tested a new variant of a patient vest containing proprietary electrodes to be used with our monitors previously under development by Signalife (the *Signalife Cardiac Vest*). We believe that our Cardiac Vest may provide a better signal in an ambulatory setting than currently-available FDA-cleared or approved electrode/wire sets since the vest, as conceived, would ensure that the electrodes remained affixed to the body in the correct location throughout the monitoring period. We also believe that our Cardiac Vest will be more convenient and comfortable for a patient, particularly since it can be easily put on or removed, the electrodes do not need to be attached to the skin using leads and gels currently used for ambulatory recording devices, and there is no loose wiring. The design is planned to allow a patient to use the vest on a 24/7 basis for extended periods of time, being removed only intermittently for showers, etc.

The Signalife Cardiac Vest is an extremely lightweight, close-fitting vest or undergarment made of stretchable material in which the electrodes are stitched into the fabric. Working with cardiologists, we successfully tested the vest during fiscal 2006 in the Champ Car Series, in which selected race-car drivers would wear the vest during races, and the data collected would be transmitted wirelessly to a modified Model 100 monitor using telemetry. It should be noted that in spite of harsh and noisy racing conditions, we were able to precisely measure ECG signals using the Cardiac Vest and our Model 100 monitor, demonstrating the efficacy of each. We are currently in the process of investigating issues relating to the commercial production of the Cardiac Vest, and have entered into preliminary discussions with an industry partner relative to the prospective distribution of this product for both typical ambulatory purposes as well as for athletic applications. Should we proceed with the product, we will need to first procure the necessary FDA approval or clearance for the vest. At this point we are still investigating the commercial viability of this product, including both the athletic market and the general ambulatory market. We can give you no assurance that we will be successful in marketing the Signalife Cardiac Vest at all or within any estimated timeframes or costs, or in procuring FDA approval or clearance for this product, or in fabricating and manufacturing durable, reliable and competitively priced versions of this product.

Intracardiac Monitor

We have completed a pre-production version of a proto-type intracardiac ECG monitor (the *Signalife Intracardiac Monitor*), and are currently designing, engineering and fabricating a production version of this product. We previously successfully tested a proto-type version of this product at the Electrophysiology Laboratories at the Cleveland Clinic Heart Center as was reported in a poster presentation at the Heart Rhythm Society in Boston in May 2006. The Signalife Intracardiac Monitor applies our proprietary physiological signal acquisition and amplification technology to read intracardiac signals procured from intracardiac catheter products. An intracardiac catheter is a flexible tube that is inserted through a vein in the leg and fed into the heart. The catheter is equipped with electrodes which allows the signal to be recorded within the heart, and the catheter data is transmitted to the monitor, which allows the physician to evaluate cardiac function, including arrhythmia, or irregular heartbeat. These readings are beneficial in that they measure signals directly from the heart, as opposed to signals read from the surface of the body as is typical in the ordinary application of heart monitors. Given our immediate focus on marketing and distributing our Fidelity 100 Monitor System and introducing our Signalife Holter Monitor and Signalife Fidelity 200 Event Recording System to market, and the complexities involved in designing, engineering and fabricating a production version of this product, we do not anticipate that we will complete this step until fiscal 2008 at the earliest.

Patient Monitoring Centers

Signalife has previously considered in the longer term developing, acquiring or entering into joint venture, licensing or other collaborative arrangements with patient monitoring centers that would work in conjunction with our products and with certain monitoring capabilities which we have internally established. Signalife s involvement with patient monitoring centers would enable us to receive a continuous stream of revenues from monitoring devices we sell, which would allow us to substantially enhance our revenues from the initial sale of such devices.

Patient monitoring centers are typically used in ambulatory settings, where a patient wears a Holter monitor or an event recorder over an extended period of time while performing his or her daily activities away from the physicians office or hospital, and the data from the Holter monitor or event recorder is transmitted to the monitoring center either by telephone or the Internet. The data is then transferred or made available to the cardiologist.

We would likely expand the services offered by our patient monitoring centers to include mobile outpatient monitoring using either our Signalife Fidelity 200 Event Recording System or a telemetry-based version of Signalife Holter Monitor in conjunction with our Cardiac Vest. At this point we are evaluating the feasibility of this project with a nationally-known research hospital which has indicated an interest in some form of participation with the company on this project.

Before making any decision relating to extending our involvement into a patient monitoring center project, there are numerous business and technical issues we would need to resolve. Further, the patient monitoring centers and software may also require FDA approval, and the server and network at the patient monitoring center would also need to be compliant with the Health Insurance Portability and Accountability Act, which requires that we meet federally mandated requirements when handling patient data. At this point we remain in the early investigation stage relative to patient monitoring centers and continuous monitoring software, and cannot provide any guidance as to any estimated timeframes as to when or even if we would formally commence or complete the project, or as to any of the estimated costs involved. Should we proceed with the project, we can give you no assurance that we will be successful with respect to patient monitoring centers, procuring the necessary FDA approval or clearance for these services, or competitively marketing these services.

EEG Products

We have initiated a study of the applicability of our technology to electroencephalogram or EEG-related applications, in particular the detection of Alzheimer s, Parkinson s and other neurological diseases. As previously discussed above, earlier versions of our amplification technology are now used in EEG equipment used to measure neurological or brain responses. We believe the enhancements Dr. Drakulic has designed since for ECG purposes may have similar application for the EEG market. As discussed below in this annual report, this activity will not impact the Teledyne licensing agreement.

Given our immediate focus on marketing and distributing our Fidelity 100 Monitor System and introducing our Signalife Holter Monitor and Signalife Fidelity 200 Event Recording System to market, we do not anticipate that we actively pursue the data collection and other activities necessary to further this product until fiscal 2008 at the earliest.

Competitive Advantages And Marketing Strategy

As discussed in *Description Of Signal Technologies; Evaluative Studies* below, Signalife believes that the Signal Technologies afford our ECG monitoring devices the ability to amplify and discriminate physiological signals in all settings, notwithstanding the existence of electromagnetic ambient noise from other sources, and in all frequency ranges, including lower-amplitude physiological signals associated with those in the lower and upper portions of the full 0.05 to 150 Hz frequency range associated with

transient heart diseases. Based upon these beliefs, Signalife is marketing or will market our ECG devices as follows:

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In the case of clinical settings where resting ECGs are typically taken, Signalife is promoting the ability of our ECG devices to allow the patient to walk around the facility or on a treadmill while the ECG is being taken, thereby allowing the physician to better identify transient heart diseases. Since competitive resting ECG devices do not presently have this ability, this should lend our ECG devices a clear competitive advantage over traditional resting ECG devices.

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In certain clinical resting settings where there is a high incidence of electromagnetic interference, such as in surgical suites, Signalife is promoting the ability of our ECG devices to provide clear and accurate signal data that is not adversely affected by the electromagnetic interference.

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In the case of ambulatory settings, where a patient wears a Holter monitor or event recorder for an extended period of time while performing his or her daily activities away from the physicians office or hospital, Signalife is promoting the ability of our ECG devices to amplify and discriminate physiological signals in the lower-amplitude physiological signals associated with those in the lower and upper portions of the full 0.05 to 150 Hz frequency range associated with transient heart diseases. Since competitive ambulatory ECG devices do not presently have this ability, this should lend our ECG devices a clear competitive advantage.

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In the case of exercise or stress settings, Signalife is promoting the ability of our ECG devices to provide clear signal data that does not need to be filtered and processed by computer software to eliminate electromagnetic noise, addressing the reliability issues arising from the use of such programs.

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The ability of our ECG devices to provide clear data output and more accurate results across the full Hz frequency ranges also allows us to provide the physician with signal data that will facilitate greater diagnostic yield , a medical term which means that the physician can more accurately and expeditiously diagnose the cardiac disease or condition, leading to better patient outcomes.

To date, the cardiac monitor market is a mature one with little innovation or product differentiation and limited market growth. Competitors principally compete on price and relatively small margins in order to maintain market share. Volume is mainly predicated on product replacement and the increased need for devices compatible with data networks. Given the product advantages afforded by our Signal Technologies, we believe that we can differentiate the benefits of our products from those of competitors and sell our products for greater prices and margins than our competitors. We also believe that our monitoring devices will cause existing versions in the market to be deemed obsolete, with will accelerate the growth of replacement sales and the overall growth of the market. The principal hurdle we must overcome in order to attain these ends will be educating prospective purchasers as to the product differences and benefits afforded by our products over competitive products.

Description of Signal Technologies; Evaluative Studies

Our patient modules operate using the Signal Technologies. The Signal Technologies are a patented amplification technology originally developed by our Chief Technology Officer, Dr. Budimir S. Drakulic, to address the electrical interference or noise issue during physiological recordings. In an effort to explore ways to accurately and objectively monitor pilot performance, the United States Air Force desired to record a pilot s neurological brain responses, consisting of tiny electrical impulses generated by the brain, to different tasks and stresses that occur in-flight using an electroencephalogram or EEG test. However, the Air Force found that the neurological signal monitoring equipment then available was not able to accurately monitor EEG in an electromagnetically-charged (i.e., noisy or artifact-intensive) environment such as the cockpit of a fighter jet or a B-52 bomber. In 1992, Dr. Drakulic led a team from the University of California at Los Angeles (*UCLA*) and the Veterans Administration in an effort to

develop a device to resolve this problem. This effort resulted in the creation by Dr. Drakulic in 1994 of a first-generation amplifier that was successfully used by the Air Force to monitor pilot EEG signals. This early version amplifier is also currently used by the National Institute of Health as well as companies such as Titan Systems and Teledyne, Inc. for purposes of monitoring different physiological signals.

The Signal Technologies were originally acquired by ARC Finance Group from Dr. Drakulic and then by Signalife from ARC Finance Group, based upon the belief of Dr. Drakulic and the principals of these companies that with the technological, development and financial assistance of these companies the capability of the technology to discriminate EEG signals, particularly in an electromagnetically-charged environment such as fighter aircraft cockpits, would have a similar application in discriminating ECG signals from ambient noise. Specifically, it was and continues to be believed by these persons that the Signal Technologies, as applied to the ECG market, would have the ability to amplify and discriminate the lower-amplitude physiological signals associated with those in the lower and upper portions of the full 0.05 to 150 Hz frequency range, thereby facilitating the ability to more clearly identify heart diseases in an ambulatory setting. In developing Signalife s initial ambulatory patient modules and overall heart monitor systems, and adopting the Signal Technologies for those modules and systems, Dr. Drakulic has since enhanced the signal processing technology such that Signalife has filed five additional patents covering these enhancements.

In order to validate our beliefs as to the performance of our technology in the ECG market, on August 30, 2004 we entered into an agreement with the Duke Clinical Research Institute at Duke University to evaluate the performance of our Fidelity 100 Monitor System against a well established high fidelity ECG monitor. Under this agreement, the Duke Clinical Research Institute under the supervision of Dr. Mitchell W. Krucoff, as principal investigator, has since designed and conducted DIVA clinical studies evaluating our Fidelity 100 Monitor System during catherization procedures at the Durham, North Carolina, Medical Center from January 2005 to December 2005. The results of the complete study, first made available in November 2006, indicate that the Fidelity 100 Monitor System provides excellent detection and quantification of transient ischemia. The results of study will be submitted for publication by Dr. Krucoff, principal investigator of DIVA study, and group of authors.

Market And Competition

Market

Cardiovascular disease accounts for 40% of all hospital revenue and approximately 37% of deaths in the United States. Over 500,000 Americans survive heart attacks every year and need to be diagnostically monitored. In the United States alone, over 280,000 patients have various heart devices implanted. The US Department of Health and Human Services estimates that heart disease costs including, hospital expenses, home care, medications and lost earnings, exceed $400 billion. Experts estimate that 85% of cardiovascular disease could be prevented or halted by sufficient early diagnosis.

According to the American Heart Association, a patient that survives the acute stage of a heart attack has a chance of illness and death that is 1.5-15 times higher than that of the general population. Signalife's patented heart monitoring technology will allow physicians to monitor patients in an ambulatory setting, giving them access to vital life-improving and life-saving information.

Competition

Each of the ECG market segments is highly concentrated with five or six companies typically accounting for a substantial majority of all sales. Our principal competitors in the resting ECG market segment are GE Healthcare, Royal Philips Electronics, Cardiac Science, Inc. and Welch Allyn, Inc. Our principal competitors in the stress ECG market are GE Healthcare, Cardiac Science, Inc, Welch Allyn, Inc. and Schiller AG. Our principal competitors in the ambulatory ECG market segment include Del Mar Reynolds Medical Ltd., GE Healthcare, Royal Philips Electronics, Cardiac Science, Inc, Mortara

Instrument, Inc., Rozinn Electronics, Inc., CardioNet, Inc., Raytel Medical Corporation, Cardiac Telecom, Inc. and Card Guard Instromedix and Lifewatch subsidiaries.

The market for heart monitoring products and services is intensely competitive, especially for small companies. Given the lack of product differentiation and intense competition, companies principally compete on price. There are no substantial barriers to entry, and we expect that competition will be intense and may increase. Many of our existing competitors may have substantially greater financial, product development, technical and marketing resources, larger customer bases, longer operating histories, better name recognition and more established relationships in the industry. As a result, certain of these competitors may be able to develop and expand their product and service offerings more rapidly, adapt to new or emerging technologies and changes in customer requirements more quickly, take advantage of acquisition and other opportunities more readily, devote greater resources to the marketing and sale of their products and services, or aggressively reduce their sales prices below the our costs. We cannot assure you that we will be able compete successfully with existing competitors or new competitors.

Marketing And Distribution Strategy

We currently distribute our products and services through a small internal sales team and a small number of independent commissioned distributors. We have recently entered into a non-exclusive independent sales representation agreement with Life Wave, LLC, to act as our sales representative in nine states in the southeast. Life Wave is a newly-formed network of 37 independent representatives with extensive experience in selling cardiac medical devices, principally cardiac rhythm management devices, to medical professionals and health care institutions. We anticipate that Life Wave will expand its reach to become a national distributor of our products. We have also recently engaged an independent distributor for Mexico. We have also entered into agreements with several firms to market, promote and otherwise introduce our products to medical professionals and health care institutions, both in the United States and internationally, and to otherwise generate product awareness.

We are also in discussions with several prospective industry partners relative to distributing our products, including an industry partner that is in the process of arranging evaluative tests of the Fidelity 100 Monitor System; an industry partner to whom we have extended a first right of marketing the Signalife Fidelity 200 Event Recording System; and an industry partner that is investigating the use of the Signalife Cardiac Vest for Holter monitor purposes. No assurance can be given that we will enter into agreements with any of these industry partners.

We have recently successfully completed a pilot program with Gold s Gym International, Inc. in which patrons of the gym at a selected facility were tested using Signalife s Fidelity 100 Monitor System in order to detect and identify cardiovascular disease that could be triggered or exacerbated by exercise programs. As part of the program, we developed a set of test protocols and procedures to address cardiac risks inherent to exercise. We are now in the process of expanding the program to fitness facilities across the country.

We are also participating in the Athletes For Life program which will focus on developing protocols to test professional and amateur athletes for cardiovascular disease and abnormalities as part of their regular training regime, and will also promote testing for impoverished communities where early detection of cardiovascular disease simply does not exist. A large number of high-profile athletes have indicated their desire both in participating in this program given the high incidence of cardiovascular abnormalities associated with athletes involved in professional sports and track and field; and also sponsoring the community outreach portion of the program given their desire to promote

community fitness and cardiovascular testing in the general community.

Manufacturing Capacity

We intend to manufacture our products both domestically and off-shore using third party FDA-certified contract manufacturers or joint-venture partners. Most of the components of our products are standard parts which are available from multiple supply sources at competitive prices. This, coupled with the lack of significant start-up costs attributable to the use of contractors, should minimize production and product costs. Currently, we have engaged one contract manufacturer, Ventrex, Inc., which has been manufacturing the Model 100 Modules used in our Fidelity 100 Monitor System since December 2005.

Research And Development

We currently conduct research and early stage development activities in-house and with engineering consultants. We retain title to all improvements or enhancements to our technology developed by or worked on by our engineering consultants under their contracts. Our research and development expenses for fiscal 2006 and 2005 were $2,694,958 and $1,328,482, respectively. None of these expenditures were borne by customers. We have budgeted $1,711,000 for research and development for fiscal 2007.

Regulatory Overview

Current Status

Our Fidelity 100 Monitor System is a Class II medical device that must be cleared by the FDA in order to be marketed within the United States. On January 28, 2004, we received FDA 510(k) clearance under the FDA s abbreviated 510(k) submission format allowing us to market our Model 100 Module as part of an overall ECG system, on the basis of it being substantially equivalent to other ambulatory monitor systems on the market which satisfy the industry s consensual ANSI/AAMI EC-38 standard for non-diagnostic monitor systems. Under the terms of the abbreviated 510(k) clearance, we are required to have supporting data in our files documenting that our Fidelity 100 Monitor System will conform to performance standards before marketing the Module 100 Module. As such, we may continue to perform engineering and design work on the Model 100 Module without resubmitting the system for further FDA 510(k) clearance unless we were to significantly alter the safety or effectives of the system as cleared by FDA. We do not currently anticipate this will occur.

FDA Regulations And Requirements

ECG heart monitor products are regulated in the United States by the Food and Drug Administration (the *FDA*) under the Medical Device Amendments of 1976 (the *Medical Device Act*), a section of the Federal Food, Drug & Cosmetic Act (the *FDC Act*). Under the Medical Device Act, medical devices are designated as Class I, II or III devices depending upon the level of control and review necessary to assure the safety and effectiveness of the device, which in turn is based upon the level of risk to the patient. ECG heart monitor products are classified as a Class II medical device, which cannot be sold in the United States unless the seller can first demonstrate or represent to the FDA pursuant to section 510(k) of the FDC Act, that the device is substantially equivalent to one or more similar devices currently on the U.S. market, referred to as predicate devices. To demonstrate substantial equivalency, the applicant must show that the new device (1) has the same intended use as the predicate device or devices, and (2) has either the same technological characteristics as the predicate device or devices, or has different technological characteristics that

do not raise new questions of safety and effectiveness. A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards and other applicable characteristics. Until the applicant receives clearance declaring a device substantially equivalent, it may not proceed to market the device within the United States.

The review period and FDA determination of substantial equivalence should be made within 90 days of submission of a 510(k) application, unless additional information or clarification or clinical studies are requested or required by the FDA. As a practical matter, the review process and FDA determination can take significantly longer than 90 days.

It should be noted that 510(k) clearance is a grandfather process. As such, 510(k) clearance does not imply that the safety, reliability and effectiveness of the medical device has been approved or validated by the FDA, but merely means that the medical device is determined to be substantially equivalent to a previously cleared commercially-related medical device.

As an alternative to the traditional 510(k) submission process, the FDA has also adopted an abbreviated or summary 510(k) submission process in cases where device-specific guidance documents or special controls have been established, or the FDA has recognized a relevant consensus standard, and the applicant certifies compliance or conformance with those documents, controls or standards. The applicant can procure abbreviated 510(k) clearance by either; (1) submitting a declaration that the applicant has in its files test data confirming that the medical device conforms to the consensus standard at the time of submission, or (2) submitting a statement that the medical device will conform to the consensus standard and that the applicant will have that supporting data in its files before marketing the device. Under either approach, the FDA reviewers will normally accept the declaration or statement without requesting the submission of information demonstrating conformity with the standard. In the case of ECG heart monitor products, the FDA has recognized the EC-38 Ambulatory Electrocardiograph, EC-11 Diagnostic ECG, and EC-13 Arrhythmia Detection and Alarm standards adopted by the American National Standards Institute or ANSI and the Association for the Advancement of Medical Instrumentation or AAMI as voluntary consensus standards for Class II 510(k) submission purposes. In the event that we make improvements to a previously-cleared device, the FDA also has a process that allows us to compare the improved device to our previously-cleared device on an expedited basis, typically 30 days.

Both domestic and foreign manufacturers and distributors of medical devices that intend to market those devices in the United States must register their establishments with the FDA and annually update the registration. Registration provides the FDA with the location of medical device manufacturing facilities and importers. In addition, all medical devices that are manufactured and imported into the United States must be listed with the FDA. Medical device listing is a means of keeping the FDA advised of the generic categories of devices an establishment is manufacturing and marketing.

Manufacturing facilities must undergo FDA inspections to assure compliance with good manufacturing practices or GMPs set forth under the quality system or QS regulation promulgated by the FDA. The quality system regulation provides a basic framework to ensure that manufacturers of finished medical devices intended for commercial distribution in the United States have in place a quality system for the design, manufacture, packaging, labeling, storage, installation and services of finished medical devices intended for commercial distribution in the United States. These regulations require that various specifications and controls be established for devices; that devices be designed under a quality system to meet these specifications; that devices be manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems and that complaints be processed. Thus, the quality system regulation helps assure that medical devices are safe and effective for their intended use. The FDA monitors device problem data and inspects the operations and records of device developers and manufactures to determine compliance with the GMPs.

Medical devices sold in the United States must also conform to general labeling requirements adopted by the FDA stipulating the content and format of product information that must be provided with the device, including information

relating to the manufacturer of, and the intended use of the device, as well as directions for use of the device.

Under Medical Device Reporting or MDR regulations established by the FDA, manufacturers, distributors and users of medical devices are required to report complaints of device malfunctions or incidents of serious injuries or deaths associated with medical devices to the FDA. The MDR regulations provide a post-surveillance mechanism for the FDA and manufacturers to identify, monitor and track significant adverse events involving medical devices for the purpose of detecting and correcting problems in a timely manner.

The FDA has established regulations governing the voluntary recall of medical devices by a manufacturer or importer should it be determined that the devices are defective, present a risk of injury, or are deceptive. Under the Medical Device Recall Authority regulation promulgated by the FDA, that agency also has the authority to order the involuntary recall of medical devices. Under the Medical Device Corrections And Removal regulations established by the FDA, manufacturers and importers are required to report to the FDA the occurrence of any correction or removal of a medical device where made to reduce a risk to health or a violation of the FDC Act.

The FDA has established regulations governing the import and export of medical devices. For a Class II medical device to be legally imported into the United States, it must meet FDA regulatory requirements. At this time, the FDA does not recognize regulatory approvals from other countries. Any Class II medical device may be legally exported from the United States without prior FDA notification or approval so long as it is in legal commercial distribution within the United States. Legal commercial distribution means that (1) the manufacturing establishment is registered with the FDA; (2) the device is listed with the FDA; (3) the sale of the device in the United States is authorized by either 510(k) notification or pre-market approval (PMA); (4) FDA labeling requirements are satisfied; and (5) the device is manufactured in accordance with GMP practices stipulated under the QS regulation. While the FDA does not place any restrictions on the export of these medical devices, certain countries may require written certification that a manufacturer or its devices are in compliance with U.S. law. In such instances the FDA will accommodate the exporter by providing a certificate of compliance called a Certificate for Foreign Government or CFG . If the medical device does not satisfying the foregoing requirements, it may be generally exported under two alternatives. First, if 510(k) clearance for the device is pending in the United States, it may be exported upon a showing that the device will reasonably obtain 510(k) clearance. In addition, the exporter must obtain a Certificate of Exportability from the FDA should the foreign country or consignee request assurance that the device complies with U.S. law. If the exporter does not intend to market the device in the United States, he may obtain a Certificate of Exportability to export the device based upon a showing that the device (1) complies with the laws of the foreign country; (2) meets the foreign purchaser s specifications; (3) is labeled for export on the shipping carton; and (4) is not sold or offered for sale in domestic commerce.

The failure of the manufacturer, importer, distributor or user to meet any of the FDA requirements imposed on it under the FDC Act or administrative regulations adopted thereunder by the FDA, may subject it to civil money penalties, administrative remedies or legal remedies under that Act or regulations.

Other U.S. Regulations And Requirements

Our heart monitor products and systems must also conform to a number of performance, safety, environmental and regulatory standards, such as those relating to electromagnetic interference, electromagnetic susceptibility, shock and current leakage, and transmission frequency. These standards include the IEC60601-2-27 requirements for the safety of electrocardiograph devices; the IEC 60601-1-2 requirements for safety and electromagnetic compatibility; the UL2601-1 medical equipment general requirements for safety, and FCC regulations under part 15, subpart C, governing allowable frequency ranges for different types of transmission devices, including medical devices.

The server and network we will use in our monitoring station to collect heart data must comply with the Health Insurance Portability and Accountability Act, which requires that we meet federally mandated requirements when handling patient data.

International Regulations And Requirements

The requirements for approval or clearance to market medical products in foreign countries vary widely. The requirements range from minimal requirements to requirements comparable to those established by the FDA. For example, many countries in South America have minimal regulatory requirements, while many others, such as Japan, have requirements at least as stringent as those of the FDA. Foreign governments do not always accept FDA approval as a substitute for their own approval or clearance procedures.

As of June 1998, the member countries of the European Union require that all medical products sold within their borders carry a Conformite Europeane Mark (*CE Mark*). The CE Mark denotes that the applicable medical device has been found to be in compliance with guidelines concerning manufacturing and quality control, technical specifications and biological or chemical and clinical safety. The CE Mark supersedes all current medical device regulatory requirements for European Union countries. In the case of a class II medical device, the CE Mark is granted based upon the manufacturer s certification of conformity with European Union guidelines, and does not require further examination of the product by a competent authority.

The FDA has issued to Signalife a Certificate to Foreign Government, which allows the importation of the Signalife Fidelity 100 Monitor System into Mexico, which conditions such importation upon written certification from the FDA that a firm or its devices are in compliance with U.S. law, including Good Manufacturing Practices and FDA labeling requirements.

We intend to apply for a CE Mark for our Fidelity 100 Monitor System in the second quarter of fiscal 2007, which will, upon grant, allow us to sell that product in the European Union. We anticipate that the approval process will be received by the third quarter of fiscal 2007.

Patents And Licenses

We hold patent number 5,678,559 issued by the United States Patent and Trademark Office for