RECOM MANAGED SYSTEMS INC DE/
Form 10KSB/A
November 09, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 10-KSB/A
AMENDMENT NO. 2

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x Annual Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2003

o Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number: _____

RECOM MANAGED SYSTEMS, INC.
(Exact 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.)

4705 Laurel Canyon Boulevard, Suite 203
Studio City, California 91607
(818) 432-4560
(Address of principal executive offices) (Zip code) (Issuer s telephone number)

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

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

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 x No o

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: x

The issuer s revenues for its most recent fiscal year (fiscal 2002) was $0.

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 $50,765,000 as of April 30, 2004.

Check whether the issuer has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court during the past five years: Yes x No o

The number of shares outstanding of each of the issuer s classes of stock as of as of April 30, 2004, the latest practicable date, was 33,345,262 common shares and 1,661,305 series A convertible preferred shares.

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.

ADVISEMENTS

The information set forth in the section of this annual report captioned *Business* is current as of April 30, 2004, 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, 2003, unless an earlier or later date is indicated in those sections.

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, 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*, and similar expressions. When reading any 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) the success of our research and development activities, the development of a viable commercial production model, and the speed with which regulatory authorizations and product launches may be achieved; (2) whether or not a market for our products develops and, if a market develops, the pace at which it develops; (3) our ability to successfully sell our products if a market develops; (4) our ability to attract the qualified personnel to implement our growth strategies, (5) our ability to develop sales, marketing and distribution capabilities; (6) our ability to obtain reimbursement from third party payers for the products that we sell; (7) the accuracy of our estimates and projections; (8) our ability to fund our short-term and long-term financing needs; (9) changes in our business plan and corporate strategies; and (10) other risks and uncertainties discussed in greater detail in the sections of this annual report, including those captioned *Plan of Operation*. 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 pubic reports filed with the United States Securities and Exchange Commission (the *SEC*). 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 annual report to reflect new events or circumstances unless and to the extent required by applicable law.

BUSINESS

Overview

Recom is a development stage 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 will be patient modules used as part of a heart monitor system to acquire, amplify and process 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. Our patient module will operate 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 amplification technology is an enhancement of an amplification technology first developed for the United States Air Force to record bioelectrical signals from a pilot s brain, known as an electroencephalogram or EEG. Earlier versions of the technology were also 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 relating to the brain.

Corporate History

Recom was originally incorporated in Delaware on January 19, 1987 under the name Mt. Olympus Enterprises Inc.. We had no specific business purpose on the date of incorporation and were inactive until October 30, 1998. On that date, we completed a reverse acquisition with J2 Technologies LLC, a California limited liability company formed on July 31, 1998, which was engaged in the business of developing, servicing and managing commercial computer networks both on-site and remotely. As a consequence of the reverse acquisition, we engaged in J2 Technologies business and changed our name to Recom Managed Systems, Inc. We were subsequently unsuccessful in this business and, on June 26, 2000, filed a voluntary petition for reorganization under Chapter 11 of the Federal Bankruptcy Code. Our plan of reorganization was confirmed by the Bankruptcy Court and the confirmation order became final on November 7, 2000. Subsequent to declaring bankruptcy, we ceased our business operations. The plan of reorganization provided for a total discharge of the company and our officers and directors from all pre-petition debts, expenses and legal causes of action which may have existed on or before the filing of the bankruptcy. The plan further provided for the consolidation of all previously issued common shares, and the issuance of additional common shares to various creditors of the company. As of December 31, 2000, following full implementation of the plan, there were 4,139,784 common shares (1,379,928 shares pre-split) issued and outstanding.

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, 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 the 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 Recom, 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 Recom or ARC Finance Group or our respective officers, directors or shareholders in connection with our acquisition of the Signal Technologies.

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The principal component of the Signal Technologies is a patented amplification technology which was originally invented by our Vice President and 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 pursuant to which Dr. Drakulic granted a limited license to that company to manufacture EEG monitor products based upon an early version of the amplification technology. This license agreement specified that Dr. Drakulic retained ownership of the original patent and underling 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 Vice President and 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. Tracy 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 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 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 a passive investment in our company. ARC Finance Group s only investment and business activity to date relates to Recom, ARC Finance Group has no investments other than Recom, sources of revenue or liabilities, and there is no past or current relationship between ARC Finance Group and Titan Systems or Teledyne Inc.

On April 11, 2003, we completed a three for one forward stock split, resulting in a total of 31,510,848 common shares being outstanding as of that date.

We do not consider Recom to be a blank check company as that term is defined in Rule 419 of Regulation C promulgated under the Securities Act of 1933, as our business plan does not contemplate our engaging in any merger or acquisition with any unidentified company, entity or person. Notwithstanding the foregoing, should we in the future identify a technology, product or business we deem advisable to acquire, we reserve the right to consider that acquisition at that time. We had previously considered the acquisition of a non-prescription heart monitor system from TZ Medical, Inc., however we have recently decided not to pursue that acquisition.

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 is 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:

- ECGs administered in the resting setting are generally given under either (1) emergency circumstances when an individual complains of symptoms typically associated with heart disease such as chest pains, shortness of breath or heart palpitations, or (2) on an annual basis for older patients as part of their annual physical examination. Most 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.

- ECGs administered in the ambulatory setting are given in an attempt to identify heart disease not evident in the resting setting. Heart disease such as cardiac ischemia and cardiac hypertrophy as well as 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.

- 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, his 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. However, 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[1] and American College of Cardiology[2] 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 Recom s ECG Products

Ambulatory Heart Monitor Systems

We are in the process of completing development work on our first product for commercialization, our battery-operated, digital 12-lead Recom Model 100 Patient Module or Model 100 Module . As discussed below, the Model 100 Module will be used as the primary component of a 12-lead ambulatory heart monitor system to acquire, process, amplify and store physiological signal data. In operation, the Model 100 Module will be used in conjunction with two accessories, a currently-available FDA-cleared or approved electrode/lead wire set which Recom has engineered the Module 100 to be compatible with and recommends for use with the module, and a currently-available personal digital assistant or PDA device which Recom has also engineered the Module 100 to be compatible with and recommends for use with the module. Once physiological data is recorded and stored, it will then be interpreted at a later date by a cardiologist using currently-available FDA-cleared or approved ECG analysis software program. By way of example, Recom currently intends to design the Model 100 Module to work with FDA-cleared and available electrodes and lead wire sets such as the ConMED D-series ECG Cable and 3M Red Dot Snap Monitoring Electrodes, and for its data to be interpreted by FDA-cleared analysis software programs marketed such as those offered by Mortara, Phillips and/or General Electric. In this annual report and, as discussed below, in Recom s regulatory filings with the FDA, we refer to the foregoing heart monitor system by which the Model 100 Module interfaces with compatible FDA-cleared or approved electrode/lead wire sets and PDAs as the Model 100 Monitor System , and the compatible electrode/lead wire sets, PDAs and ECG analysis software as the *ancillary products*

The Model 100 Monitor System is an ambulatory patient heart monitor or recording system that will allow a patient s heart to be continuously monitored 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. As previously noted, the primary component of the monitor system is the Model 100 Module, a compact device approximately 4 x 3.5 x 1.5 inches in size and 5.5 oz. in weight, which acquires the physiological signals from the patient by means of the electrodes; processes and amplifies the signals using the Signal Technologies; and then transmits the signal data wirelessly to the PDA to be stored as a file on a flash card. Patients using the Model 100 System will be able to move around freely while data is collected by patient module and sent in real time from the patient module to the PDA and stored on the flash card. At the conclusion of the recording period, the patient returns the Model 100 Monitor System to the cardiologist, who retrieves the flash card and places it in a reading analysis station on which an ECG analysis software program is installed. The raw ECG recorded data is then analyzed by the software providing the cardiologist with the results for interpretation. The Model 100 Monitor System is a non-diagnostic system insofar as it records, processes and stores physiological signals, but does not contain diagnostic software for signal interpretation.

The Model 100 Module can be used with any FDA-cleared or approved electrode/lead wire set or PDA, and the signal data produced by the Model 100 Monitor System can be interpreted by any FDA-cleared or approved ECG analysis software, so long as we have listed that equipment or software as being compatible with the module or signal data produced by the monitor system in our packaging in accordance with FDA labeling regulations. For example, the Model 100 Module can be connected to a patient via commercially available cable and electrodes as discussed above. As a practical matter, the determination and provision of the electrode/lead wire set and PDA to be used with the Model 100 Module will be made by patient s cardiologist and the cardiologist will also use his software program to manage and interpret the data in making his diagnosis. We are currently identifying one or more ancillary products that we would recommend for use with the Model 100 Module as part of the monitor system. Upon our identification of the ancillary products with which the Model 100 Module can be operated, we will modify the module to ensure computability. Once we have completed these steps, we must design and engineer a pre production model for testing to provide assurance that the device is compliant to the necessary performance, safety and regulatory test requirements and to further assure the device will be durable, reliable and competitively priced. We anticipate that we will complete a pre production model of the Model 100 Module that is fully compliant with its ancillary products by the end of

2004.

[1] ACC/AHA 2002 Guideline Update for Exercise Testing, Gibbons RJ et al.

[2] Exercise Standards for Testing and Training: S Statement for Healthcare Professionals, Fletcher GF et al, Circulation 104:1694-1740, published on October 2, 2001.

Our Model 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 Monitor System, i.e., our Model 100 Module used in conjunction with its FDA-cleared or approved ancillary products, 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 Model 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 anticipate this will occur.

No assurance can be given that we will be successful in designing and engineering a durable, reliable and competitively priced production version of the Model 100 Module.

Patient Vest And Electrodes

We are also in the early stages of investigating the development of a patient vest containing electrodes to be used with our ambulatory heart monitor systems as an alternative to the currently-available FDA-cleared or approved electrode/wire sets. We believe that a patient vest may provide a better signal in an ambulatory setting than the current use of electrodes 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 the vest will be more convenient and comfortable for a patient. 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. We must address two engineering issues in developing this vest. First, we need to develop an electrode which can be incorporated into the vest to monitor the patient s heart signal, thus replacing the use of leads and gels currently used in recording ECGs. Second, we need to design the vest in such a fashion that it not only holds the electrode against the body at the correct locations and in the proper manner, but it also can be adapted to fit patients with different heights, weights and physiques. At this point we have not ascertained whether we will be able to develop a workable vest that is not too bulky or otherwise impracticable to wear. We are also in the early stages of investigating the development of an improved electrode to be used with our system. Both the ECG patient vest and new ECG electrodes as presently conceptualized will require FDA approval or clearance. We have not to date determined the cost or timeframe to procure FDA approval or clearance.

As noted above, at this point we are currently in the early investigation stage relative to the development of the patient vest and enhanced electrodes, and have provided estimates as to costs of continuous research and timing of these programs in the section captioned *Plan of Operation* below. Notwithstanding the forgoing, we can give you no assurance that we will be successful in developing the patient vest or enhanced electrodes at all or within the timeframes or at the costs estimated, or in procuring FDA approval or clearance for these products, or in designing and engineering durable, reliable and competitively priced production versions of any of these products.

Monitoring Centers

As previously noted, our Model 100 Module will acquire physiological signals from a patient and transmit the signal data wirelessly to the PDA to be stored as a file on a flash card, which will be delivered to the cardiologist for download and analysis. In the longer term we intend to investigate the adaptation of our modules to continuously transmit data wirelessly over the Internet to a monitoring center. This will allow the cardiologist to access the patient record for analysis at anytime by simply logging into our secure server over the Internet, thereby avoiding the necessity of delivering the flash card. We are also currently in the early stages of conducting investigation and development work on software that could be used as part of a continuous preventive monitoring program using our monitoring center. The establishment of a monitoring center will enable us to receive a continuous stream of revenues from modules we sell. Several competitors currently offer monitoring services using a variety of transmission methods, such as the telephone and the Internet, so the introduction of our monitoring system would not be considered to be novel. We would either develop our own monitoring centers or acquire an ongoing monitoring business. In addition to obtaining FDA approval or clearance for our monitoring center and software, our server and network will 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. We have not to date determined the cost or timeframe to develop procure FDA approval or clearance.

At this point we are currently in the early investigation stage relative to the creation of software to be used for a preventive monitoring program referenced above, and have provided estimates as to costs of continuous research and timing of the program in the section captioned *Plan of Operation* below. We do not anticipate that we will commence development activities with respect to the creation or acquisition of a monitoring system for a least one year, and do not currently have any firm estimates as to the cost to develop or the timing to introduce such a system. We can give you no assurance that we will be successful in developing the monitoring centers or software as discussed above at all or within the timeframes or at the costs estimated, or in procuring FDA approval or clearance for these products and services, or in competitively marketing these products and services.

Description of Signal Technologies

Our Model 100 Module will operate using the Signal Technologies. The Signal Technologies are a patented amplification technology originally developed by our Vice President and Chief Technology Officer, Dr. Budimir S. Drakulic, to address the electrical interference or noise issue. 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 environment such as the cockpit of a fighter jet or a B-52 bomber. In 1992, Dr. Drakulic led a team from 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 Recom from ARC Finance Group, based upon the belief of Dr. Drakulic and the principals of these companies that 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 electromagnetic 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 Recom 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 Recom has filed three additional patents covering these enhancements. Since commercial models of our Model 100 System have not yet been commercially completed or tested, no assurance can be given that the Signal Technologies will perform as anticipated in the ECG setting.

EEG Products

We intend in the future to devote a portion of our development activities to electroencephalogram or EEG-related applications of our technology, for application in 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.

Competition

Our principal competitors in the ambulatory heart monitor market include CardioNet, Inc., which markets a 3-lead, ambulatory ECG monitor system claimed to record and wirelessly transmit physiological data by radiofrequency (RF) to a handheld PDA for subsequent modem or Internet transmission; Cardiac Telecom, Inc., which markets an ambulatory heart monitor system claimed to wirelessly transmit ECG data by way of a processor/phone-connected station; Raytel Medical, which markets an ambulatory heart monitor system claimed to transmit data by telephone; Mortara Instrument, which manufacturers and markets a 12-lead Holter ECG system; and Card Guard, which markets event recorders as well as operating monitoring centers through its two divisions in the United States, Instromedix and Lifewatch.

The market for heart monitoring products and services is intensely competitive and characterized by rapidly changing technology, evolving industry standards, and price competition. 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.

Market Size

Cardiovascular disease is the leading cause of death in the industrialized world. According to the American Heart Association s *Heart Disease and Stroke Statistics-2004 Update* :

- Heart disease and stroke, the principal components of cardiovascular disease, claim more lives in the United States each year than the next five leading causes of death combined;

- Approximately 61,800,000 people in the United States suffer from one or more types of cardiovascular disease each year;

    - Approximately 950,000 lives were claimed by cardiovascular diseases in the United States in 1999;

- Patients who have suffered heart attacks in the United States number 7.3 million, congestive heart failure 4.7 million, arrhythmia 2.0 million, and angina 6.4 million;

- Approximately one-sixth of all people in the United States killed by cardiovascular disease are under the age of 65; and

- In 2004 the estimated direct and indirect healthcare cost of cardiovascular disease in the United States will be $368.4 billion.

The Center for Disease Control has stated that, if all forms of major cardiovascular disease were eliminated, life expectancy would rise by almost seven years while, in comparison, if all forms of cancer were eliminated, the gain in life expectancy would only be three years.

Based upon the foregoing statistics, we believe that patients with any of these health problems would most likely, benefit from Recom s heart monitoring technology and systems.

Marketing And Distribution Strategy

Our current plans are to market and distribute our ambulatory patient modules under our own label. We anticipate that we will delegate most sales, marketing and distribution activities for our patient modules to third party, medical-device marketing and distribution companies on a regional basis, while creating a small internal sales, marketing and distribution management staff to oversee these activities and to explore joint venture relationships. In the case of the resting and exercise heart monitoring systems we anticipate developing at some future date, we anticipate licensing our patient module designs and technologies to established medical device manufacturers and distributors, who will most likely, incorporate them into their own systems.

Manufacturing Capacity

To date we have fabricated our prototypes and proof of concept devices in-house and with engineering consultants. Our manufacturing strategy dictates that we will rely upon third party FDA-certified contract manufacturers or joint-venture partners both domestically and off-shore to satisfy production requirements when we are able to introduce our products to market. Most of the components of our products are standard parts which will be available from multiple supply sources at competitive prices. This, coupled with the significant start-up cost advantages associated with contractors, particularly off-shore contractors, should minimize production and product costs.

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 2003 and 2002 were $497,631 and $67,500, respectively. None of these expenditures were borne by customers. We have budgeted $1,000,000 for research and development for fiscal 2004.

Regulatory Overview

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.

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 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 requireme