SIGNALIFE, INC.
Form SB-2
September 17, 2007

As filed with the Securities and Exchange Commission on September 17, 2007

Commission File No. 333 _____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form SB-2

Registration Statement Under The Securities Act Of 1933

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Signalife, Inc.

(Name of small business issuer in its charter)

Delaware	**3845**	**87-0441351**
(State or other jurisdiction of incorporation or organization)	**(Primary Industrial Code)**	**(I.R.S. Employer Identification No.)**

Lowell T. Harmison
President and Chief Operating Officer

4705 Laurel Canyon Blvd., Suite 203
Studio City, California 91607
(818) 232-4560
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)
(Name, address, including zip code, and telephone number, including area code, of agent for service of process)

Copies to

John M. Woodbury, Jr., Esq.
7251 Owensmouth Ave, Suite 7
Canoga Park, California 91303
(818) 883-1776

Approximate date of proposed sale to public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act,

please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _

If this Form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o __

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o __

If delivery of this prospectus is expected to be made pursuant to Rule 434, please check the following box: o

Calculation of Registration Fee

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Offering Price Per Share	Proposed Aggregate Offering Price	Amount of Registration Fee
Common stock	4,375,730	$1.33(3)	$ 5,819,720.90	$ 178.67
Common stock (2)	1,000,000	$1.00(4)	$ 1,000,000.00	$ 30.70
Common stock (2)	500,000	$2.00(4)	$ 1,000,000.00	$ 30.70
Total	5,875,730		$ 7,819,720.90	$ 240.07

(4)

Pursuant to SEC Rule 416(a), also covers additional common shares that may be offered to prevent dilution as a result of stock splits, stock dividends or similar transactions relating to these securities.

(2)

Represents common stock reserved for issuance by the registrant with respect to the prospective exercise of common share purchase warrants at the election of the holder of those warrants.

(3)

Pursuant to SEC Rule 457(h)(1) and 457(c), the filing fee is computed upon the basis of the average of the high and low prices reported by the American Stock Exchange as of the close of market on September 6, 2007.

(4)

Pursuant to SEC Rule 457(h)(1), the filing fee is computed based upon the exercise price for the underlying options or warrants.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED SEPTEMBER 17, 2007

Prospectus

5,875,730 Common Shares

This prospectus relates to the offer and sale by some of our shareholders during the period in which the registration statement containing this prospectus is effective of up to 5,875,730 common shares consisting of up to:

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4,375,730 currently issued and outstanding common shares; and

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1,500,000 common shares issuable by the company upon the prospective exercise of currently issued and outstanding securities purchase warrants at the election of the holder of those warrants.

This offering is not being underwritten. The common shares offered under this prospectus may be sold by the selling shareholders on the public market, in negotiated transactions with a broker-dealer or market maker as principal or agent, or in privately negotiated transactions not involving a broker or dealer. We will not receive any of the proceeds from those sales.

Our common shares trade on the American Stock Exchange under the trading symbol SGN .

Please read this prospectus carefully. It describes our company, finances, products and services. Federal and state securities laws require that we include in this prospectus all the important information that you will need to make an investment decision.

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An investment in the common shares offered for sale under this prospectus involves a high degree of risk. You should purchase our securities only if you can afford losing your entire investment.
See Risk Factors beginning on page 5 of this prospectus.

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Neither the United States Securities and Exchange Commission nor any state securities commission has approved or disapproved of the common shares offered for sale under this prospectus or the merits of that offering, or has determined that this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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The date of this Prospectus is September 17, 2007

4705 Laurel Canyon Blvd., Suite 203, Studio City, California 91607

(818) 432-4560

The information in this prospectus is not complete and may be changed. We have filed a registration statement containing this prospectus with the Securities and Exchange Commission. The common stock offered for sale under this prospectus may not be offered for sale or sold until that registration statement is declared effective by the Securities and Exchange Commission. This prospectus is not an offer to sell the common shares and doesn t solicit an offer to purchase the common shares in any jurisdiction where this offer or sale is not otherwise permitted

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TABLE OF CONTENTS

PROSPECTUS SUMMARY

This summary highlights important information about our company and business. Because it is a summary, it may not contain all of the information that is important to you. To understand this offering fully, you should read this entire prospectus and the financial statements and related notes included in this prospectus carefully, and in particular that section of this prospectus captioned *Risk Factors*. Unless the context requires otherwise, *Signalife*, *we*, *us*, *our* a similar terms refer to Signalife, Inc.

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 prospectus 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.

The Company And Business

Signalife, Inc. 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, the Signalife *Fidelity 100 Monitor System* or *Fidelity 100*, is a heart monitoring system that uses our proprietary Model 100 patient module to acquire, amplify and process physiological signals associated with a patient s cardiovascular system. Heart monitor systems are used in a variety of medical settings. For example, they are used to collect physiological data for electrocardiogram or ECG tests for the purpose of detecting and identifying cardiovascular disease, and also used to monitor the condition of the heart during surgical procedures. Our patient module operates using our proprietary patented signal acquisition and amplification technology, 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. Our proprietary signal acquisition and amplification technology provides the capability to collect, enlarge and process physiological signals in a manner that discriminates them from ambient or background electromagnetic noise, thereby facilitating the examination of the signal data for diagnostic purposes.

The *Fidelity 100 Monitor System* is marketed 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* is 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.

Our initial marketing efforts for the *Fidelity 100* since its introduction have been extremely limited to date principally due to performance issues with third-party distributors and sales agents to whom we originally delegated sales authority, our limited internal sales and marketing support functions and personnel, and the focus of prior management on other activities. We have only recently launched a company-sponsored program to aggressively market and promote the *Fidelity 100* in the United States, in which we will rely upon new senior management and directors to market our products within the United States to selected marquee hospitals and physician groups, and are re-evaluating the use of independent distributors.

We are also currently working on a number of products using our proprietary signal acquisition and amplification technology that are in the late development stage and which we expect to introduce to market in either late 2007 or by the end of 2008. These products include the Signalife *Fidelity 200 Event Recording*

System or *Fidelity 200* , the Signalife *Fidelity 300 Holder Monitor* or *Fidelity 300* , the Signalife *Fidelity 400 Intracardiac Monitor* or *Fidelity 400* , and the Signalife *Cardiac Vest*.

The Signalife *Fidelity 200 Event Recording System* is a direct-to-consumer non-prescription credit card-sized heart monitoring device which has been specifically designed to be used in conjunction with monitoring centers. We anticipate that we will sell the *Fidelity 200* to consumers through retail outlets such as drug stores, retail pharmacies, and major retail discount chains. The consumer will then separately subscribe to a monitoring service that is compatible with the device. We anticipate that the production version will be completed and brought to market by the end of fiscal 2007.

The *Fidelity 300* is a three-lead ambulatory Holter monitor which will be used while the patient carries out his or her daily activities away from the physicians office or hospital to collect ECG data relating to arrhythmia and other transient heart disease. Specifically, the data is acquired, processed, amplified and stored in a computer storage chip contained in the *Fidelity 300*, and then downloaded by the physician at a later date when the patient returns to the physician s office. The Fidelity 300 will allow up to thirty days of data to be recorded, satisfying physician needs for a more extensive database, unlike other Holter markets currently on the market that record only for a period of 24 to 48 hours. We anticipate a production version of this product will be completed and brought to market at the end of 2008 at the earliest.

The Signalife *Cardiac Vest*, developed in conjunction with the Champ Car World Series, is an extremely lightweight, close-fitting vest that will be used as a more effective, convenient and comfortable alternative for the electrode and lead sets customarily used with ambulatory cardiac monitors. 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 anticipate a production version of this product will be completed and brought to market at the end of 2008 at the earliest.

We are also actively pursuing other marketing alternatives. For example, we have recently successfully completed a pilot program in which patrons of a gym were tested using the *Fidelity 100* in order to detect and identify cardiovascular disease that could be triggered or exacerbated by exercise programs. 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.

As of September 6, 2007, we had issued and outstanding or accrued for issuance a total of: (1) 51,781,538 common shares (as that term is defined in that section of the prospectus captioned *Description Of Equity Securities*); (2) 14,574 series A preferred shares (as that term is defined in that section of the prospectus captioned *Description Of Equity Securities*), plus an additional 38,619 unissued series A preferred shares accrued for issuance as dividends through June 30, 2007; and (3) stock purchase options and warrants entitling the holders to purchase up to 10,142,586 and 179,292 common shares and series A preferred shares, respectively, at weighted average exercise prices of $2.20 and $3.00 per share, respectively.

Our corporate offices are located at 4705 Laurel Canyon Blvd., Suite 203, Studio City, California. Our telephone number is (818) 432-4560.

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

The Offering

This prospectus relates to the offer and sale by some of our shareholders during the period in which the registration statement containing this prospectus is effective of up to 5,875,730 common shares consisting of up to:

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4,375,730 currently issued and outstanding common shares; and

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1,500,000 common shares issuable by the company upon the prospective exercise of currently issued and outstanding securities purchase warrants at the election of the holder of those warrants.

The outstanding common shares offered under this prospectus may be sold by the selling shareholders on the public market, in negotiated transactions with a broker-dealer or market maker as principal or agent, or in privately negotiated transactions not involving a broker or dealer. Information regarding the selling shareholders, the common shares they are offering to sell under this prospectus, and the times and manner in which they may offer and sell those shares is provided in the sections of this prospectus captioned *Selling Shareholders* , *Registration Rights* and *Plan of Distribution* . We will not receive any of the proceeds from those sales. Should the selling shareholders in their discretion exercise any of the common share purchase warrants underlying the common shares offered under this prospectus, we would, however, receive the exercise price for those warrants. The registration of common shares pursuant to this prospectus does not necessarily mean that any of those shares will ultimately be offered or sold by the selling shareholders, or that any of the common share purchase warrants underlying the common shares offered under this prospectus will be exercised.

The common shares offered for sale under this prospectus include a total of 2,956,830 common shares held by YA Global Investments, L.P. (*YA Global Investments*), and 1,500,000 common shares issuable to that investor upon exercise of common stock purchase warrants granted to that investor, in connection with a private placement that closed on August 16, 2007 pursuant to which we raised gross proceeds of $2,000,000. Also included for sale under this prospectus are 1,404,495 common shares issued to YA Global Investments as compensation for entering into a Standby Equity Distribution Agreement concurrently with the aforesaid private placement. Also included for sale under this prospectus are 15,045 common shares issued to Newbridge Securities Corporation as compensation for acting as Signalife s exclusive placement agent in connection with the aforesaid transactions. For more complete information as to the aforesaid transactions, see those sections of this prospectus captioned *Management s Discussion And Analysis Of Financial Condition And Results of Operations Liquidity And Capital Resources* and *Registration Rights* .

Summary Financial Data

The following tables summarize the statements of operations and balance sheet data for our company for the periods or as of the dates indicated, respectively:

	Six Months Ended June 30,		Year Ended December 31,	
Statement of Operations Data	**2007**	**2006**	**2006**	**2005**
	(unaudited)	(unaudited)		
Product Sales	$	$	$ 190,170	$
Costs of products sold	$	$	$ 42,316	$
Gross profit	$	$	$ 147,854	$
Research and development expenses	$ 622,731	$ 428,113	$ 2,694,958	$ 1,328,482
General and administrative expenses	$ 7,508,202	$ 5,367,609	$ 10,806,932	$ 6,224,105
Loss from operations	$ (8,130,933)	$ (5,795,722)	$ (13,354,036)	$ (7,552,587)
Other income and expense	$ 554,039	$ 569,031	$ 1,637,910	$ 1,108,101
Net loss	$ (7,576,894)	$ (5,226,691)	$ (11,716,126)	$ (8,660,688)
Basic and diluted loss per share attributable to common stockholders	$ (0.17)	$ (0.14)	$ (0.30)	$ (0.23)
Weighted average shares outstanding, basic and diluted	44,483,645	38,804,542	39,333,720	37,298,692

Balance Sheet Data:	**June 30, 2007**	**December 31, 2006**

	(unaudited)	
Current assets		
	$ 288,734	$ 3,644,454
Total assets		
	$ 3,619,519	$ 4,520,287
Current liabilities		
	$ 579,884	$ 1,575,668
Total liabilities		
	$ 579,884	$ 1,575,668
Total stockholders equity		
	$ 3,039,635	$ 2,944,619
Total liabilities and stockholders equity		
	$ 3,619,519	$ 4,520,287

RISK FACTORS

An investment in our common shares involves a high degree of risk and is subject to many uncertainties. These risks and uncertainties may adversely affect our business, operating results and financial condition. In such an event, the trading price for our common shares could decline substantially, and you could lose all or part of your investment. In order to attain an appreciation for these risks and uncertainties, you should read this prospectus in its entirety and consider all of the information and advisements contained in this prospectus, including the following risk factors and uncertainties.

Risks Relating To Our Business

Our limited operating history will make it difficult for you to predict our future operating results and to otherwise assess or predict the likelihood of our business success.

While we introduced our first heart monitoring product, the *Fidelity 100 Monitor System*, in late 2006, we have only recently launched a company-sponsored program to aggressively market and promote this product in the United States and have limited sales to date. Prior to the introduction of the *Fidelity 100*, we were a development stage company solely engaged in research and development activities. Our limited operating history will make it difficult, if not impossible, to predict future operating results and to assess the likelihood of our business success in considering an investment in our company.

We have nominal sales revenues to date and have accumulated losses since our inception. Our continued inability to generate revenues and profits could cause us to go out of business.

We have incurred cumulative net losses before preferred dividends available to common shareholders in the amount of $42,375,550 from our inception through June 30, 2007. We project that we will not be cash flow positive based solely on projected sales and service revenues less manufacturing, general and administrative, marketing expenses and other operating costs for an indefinite period of time. We anticipate that we will continue to incur substantial operating losses for the foreseeable future, notwithstanding any anticipated revenues we may receive in the near future.

If we are unable to raise additional working capital, we will be unable to fully fund our operations and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately our going out of business.

As noted in the prior risk factor, we only recently introduced our first heart monitoring product, the *Fidelity 100 Monitor System*, to market and commenced commercial sales of that product, and further anticipate that after such introduction we will continue to be cash flow negative due to our anticipated costs exceeding our anticipated revenues for an indefinite period of time. We believe that our currently available working capital and line of credit with SES Capital and the pending investment and standby equity purchase arrangement with YA Global Investments, L.P., will be sufficient to continue our business for at least the next twelve months (although the standby equity purchase arrangement is subject to a number of conditions and restrictions which may limit our ability to sell common shares under that facility, including our inability to make sales to YA Global to the extent such sales would increase its holdings to more than 9.99% of our outstanding common shares calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934 (the *Exchange Act*)). Should our costs and expenses prove to be greater than we

currently anticipate, or should we change our current business plan in a manner

that will increase or accelerate our anticipated costs and expenses, such as through an acquisition of new products, the depletion of our working capital would be accelerated. To the extent it becomes necessary to raise additional cash in the future as our current cash and working capital resources are depleted, we will seek to raise it through the public or private sale of debt or equity securities, the procurement of advances on contracts or licenses, funding from joint-venture or strategic partners, debt financing or short-term loans, or a combination of the foregoing. We may also seek to satisfy indebtedness without any cash outlay through the private issuance of debt or equity securities. Other than our line of credit with SES Capital and the pending investment and standby equity purchase arrangement with YA Global Investments, we currently do not have any binding commitments for, or readily available sources of, additional financing. We cannot give you any assurance that we will be able to secure the additional cash or working capital we may require to continue our operations.

Even if we are able to raise additional financing, we might not be able to obtain it on terms that are not unduly expensive or burdensome to the company or disadvantageous to our existing shareholders.

Even if we are able to raise additional cash or working capital through the public or private sale of debt or equity securities, the procurement of advances on contracts or licenses, funding from joint-venture or strategic partners, debt financing or short-term loans, or the satisfaction of indebtedness without any cash outlay through the private issuance of debt or equity securities, the terms of such transactions may be unduly expensive or burdensome to the company or disadvantageous to our existing shareholders. For example, we may be forced to sell or issue our securities at significant discounts to market, or pursuant to onerous terms and conditions, including the issuance of preferred stock with disadvantageous dividend, voting or veto, board membership, conversion, redemption or liquidation provisions; the issuance of convertible debt with disadvantageous interest rates and conversion features; the issuance of warrants with cashless exercise features; the issuance of securities with anti-dilution provisions; and the grant of registration rights with significant penalties for the failure to quickly register. If we raise debt financing, we may be required to secure the financing with all of our business assets, which could be sold or retained by the creditor should we default in our payment obligations. We also might be required to sell or license our products or technologies under disadvantageous circumstances we would not otherwise consider, including granting licenses with low royalty rates and exclusivity provisions.

Our sales, marketing and distribution capabilities are currently in the initial stages of development and are limited in manpower and financial resources, which limits our ability to rapidly penetrate the markets with our products and to generate revenue growth

Our initial marketing efforts for the *Fidelity 100* since its introduction have been extremely limited to date principally due to performance issues with third-party distributors and sales agents to whom we originally delegated sales authority, our limited internal sales and marketing support functions and personnel, and the focus of prior management on other activities. We have only recently launched a company-sponsored program to aggressively market and promote this product in the United States, in which we will rely upon new senior management and directors to market our products within the United States to selected marquee hospitals and physician groups, and are re-evaluating the use of independent distributors. Going forward, we also intend to develop a more effective internal sales and marketing team. Our ability to actively market and promote our products will require significant amounts of capital that would be diverted from other uses. The distribution of our products and consequential revenue growth will therefore be limited as these marketing and distributions channels grow and funding becomes available. While we are in discussions with a number of large third party marketing and distribution partners with the manpower and financial resources to more quickly and aggressively

promote our products, there is no assurance that we will enter into an agreement with these potential partners on acceptable terms or at all.

We intend to rely upon the third-party FDA-approved manufacturers or suppliers to manufacture our heart monitoring products. Should these manufacturers fail to perform as expected, we will need to develop or procure other manufacturing sources, which would cause delays or interruptions in our product supply and result in the loss of significant sales and customers.

We currently have no internal manufacturing capability, and will rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. We have recently entered into a contract manufacturing agreement with a private-label manufacturer to manufacture our Model 100 Monitors and package our Model 100 Monitor System. We cannot give you any assurance that this contract manufacturer or any other contract manufacturer or supplier we procure will be able to supply our product in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications. Further, should we be forced to manufacture our products, we cannot give you any assurance that we will be able to develop an internal manufacturing capability or procure third party suppliers.

We are dependent for our success on a few key executive officers. Were we to lose one or more of these key executive officers, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of working capital.

Our success depends to a critical extent on the continued efforts of services of our executive management team comprised of Dr. Lowell T. Harmison, our President and Chief Operating Officer, and Dr. Budimir S. Drakulic, our Chief Technology Officer. Were we to lose one or more of these key executive officers, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of working capital. We are currently under discussions with Dr. Harmison in connection with entering into an employment agreement. Dr. Drakulic is employed as a consultant under a loan-out agreement through June 26, 2016. None of these agreements will preclude any of these key officers from leaving the company, and no assurance can be given that we will enter into an employment agreement with Dr. Harmison. We currently maintain key man life insurance policies in the amount $3 million with respect to Dr. Drakulic which will assist us in recouping some of our costs in the event of the death of that officer.

Our products are highly regulated. We will not be able to introduce our products to market if we cannot obtain the necessary regulatory approvals. If we are unable to obtain regulatory approvals for our products in selected key markets at all or in a timely manner, we will not be able to grow as quickly as expected, and the loss of anticipated revenues will also reduce our ability to fully fund our operations and to otherwise execute our business plan. Our failure to receive the regulatory approvals in the United States would likely cause us to go out of business.

The manufacture, sale, promotion and marketing of our heart monitoring products and other products we intend to develop are subject to regulation by the Food and Drug Administration (*FDA*) and similar government regulatory bodies in other countries. As we develop or obtain new products we will be required to determine what regulatory requirements, if any, we must comply with in order to market and sell our products in the United States and worldwide. The process of obtaining regulatory approval

could take years and be very costly, if approval can be obtained at all. If we fail to comply with these requirements, we could be subjected to enforcement actions such as an injunction to stop us from marketing the product at issue or a possible seizure of our assets. We intend to work diligently to assure compliance with all applicable regulations that impact our business. We can give you no assurance, however, that we will be able to obtain regulatory approval for all of our products. We also cannot assure you that additional regulations will not be enacted in the future that would be costly or difficult to satisfy.

Because we are not diversified, we are subject to a greater risk of going out of business should our single proposed product line fail.

The only business opportunities we are presently pursuing are the heart monitoring or ECG market and, later, using the same technology, the neurological brain scan or EEG market. Unlike many established companies that are diversified, we do not presently have other businesses, properties, investments or other income producing assets upon which we could rely upon should our single product line fail, thereby increasing the risk of our going out of business.

Many of our customers will rely upon third party reimbursements from third party payors to cover all or a portion of the cost of our products. If third party payors do not provide reimbursement for our products, we will not be able to grow as quickly as expected, and the loss of anticipated revenues will also reduce our ability to fully fund our operations and to otherwise execute our business plan.

We intend to sell our heart monitoring products to individual patients and doctors, hospitals and clinics who will seek reimbursement from various third party payors, including government health programs, private health insurance plans, managed care organizations and other similar programs. We can give you no assurance that reimbursement will be available from third party payors at all, or for more than a nominal portion of the cost of our products.

Our inability to protect our intellectual property rights could allow competitors to use our property rights and technologies in competition against our company, which would reduce our sales. In such an event we would not be able to grow as quickly as expected, and the loss of anticipated revenues will also reduce our ability to fully fund our operations and to otherwise execute our business plan.

We rely on a combination of patent, patent pending, copyright, trademark and trade secret laws, proprietary rights agreements and non-disclosure agreements to protect our intellectual properties. We cannot give you any assurance that these measures will prove to be effective in protecting our intellectual properties. We also cannot give you any assurance that our existing patents will not be invalidated, that any patents that we currently or prospectively apply for will be granted, or that any of these patents will ultimately provide significant commercial benefits. Further, competing companies may circumvent any patents that we may hold by developing products which closely emulate but do not infringe our patents. While we intend to seek patent protection for our products in selected foreign countries, those patents may not receive the same degree of protection as they would in the United States. We can give you no assurance that we will be able to successfully defend our patents and proprietary rights in any action we may file for patent infringement. Similarly, we cannot give you any assurance that we will not be required to defend against litigation involving the patents or proprietary rights of others, or that we will be able to obtain licenses for these rights. Legal and accounting costs relating to prosecuting or defending patent infringement litigation may be substantial.

We also rely on proprietary designs, technologies, processes and know-how not eligible for patent protection. We cannot give you any assurance that our competitors will not independently develop the same or superior designs, technologies, processes and know-how.

While we have and will continue to enter into proprietary rights agreements with our employees and third parties giving us proprietary rights to certain technology developed by those employees or parties while engaged by our company, we can give you no assurance that courts of competent jurisdiction will enforce those agreements.

Risks Relating To An Investment In Our Securities

There can be no assurance that our common shares will continue to be listed on AMEX

On June 27, 2007, Signalife received a deficiency letter from the American Stock Exchange (*AMEX*) pursuant to which it indicated that the company s current stockholder s equity of approximately $3.2 million at the time had fallen to less than the $4 million and $6 million required for continued listing under AMEX Rules 1003(a)(ii) and (a)(iii), respectively. These minimum stockholders equity thresholds were triggered by a recent decline of Signalife s market capitalization for a thirty-day period to less than $50 million, which previously exempted Signalife from these requirements. In response to the letter, on July 26, 2007, Signalife submitted to AMEX a plan for so increasing the company s stockholder s equity for AMEX s review and acceptance. This plan will need to be implemented by December 29, 2008 or such earlier date as AMEX deems reasonable. AMEX is currently reviewing Signalife s plan, and Signalife anticipates a response within the near future. If Signalife s market capitalization were to return to levels above $50 million for a thirty-day period (which has recently occurred), then the plan will not need to be implemented. In the event that our common shares were no longer to be listed on AMEX, whether by reason of AMEX s ultimate rejection of Signalife s plan, or Signalife s failure to increase stockholder s equity to the requisite $4 million and $6 million required by AMEX, Signalife would seek to trade its common shares on the Over-The-Counter Bulletin Board (*OTCBB*) as previously done before listing our common shares on AMEX. Such an event could have an impact on the trading price of our common shares. No guarantee can be given that AMEX will accept the plan or that our market capitalization will continue to exceed $50 million.

Our common shares are sporadically or thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares

Our common shares have historically been sporadically or thinly traded, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unestablished company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without a material reduction in share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained. Due to these conditions, we can give you no assurance that you will be able to

sell your shares at or near ask prices or at all if you need money or otherwise desire to liquidate your shares.

The market price for our common shares has a small and thinly-traded public float and is particularly volatile given our status as a company which has only recently introduced its products to market, and our limited operating history, nominal revenues and lack of profits to date, all of which could lead to wide fluctuations in our share price. The price at which you purchase our common shares may not be indicative of the price that will prevail in the trading market. You may be unable to sell your common shares at or above your purchase price, which may result in substantial losses to you. The volatility in our common share price may subject us to securities litigation.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. The volatility in our share price is attributable to a number of factors. First, we have relatively few common shares outstanding in the public float since most of our shares are held by a small number of shareholders. In addition, as noted above, our common shares are sporadically or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our shareholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without a material reduction in share price. Secondly, we are a speculative or risky investment due to our limited operating history, nominal revenues and lack of profits to date, and uncertainty of future market acceptance for our products. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management s attention and resources.

The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; acceptance of our products and services as viable market solution; government regulations, announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect that the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

Since a single shareholder currently beneficially owns more than one-third of our outstanding common shares, that shareholder retains the ability to influence or control our management and the outcome of corporate actions requiring shareholder approval notwithstanding the overall opposition of our other shareholders. This concentration of ownership could discourage or prevent a potential takeover of our company that might otherwise result in you receiving a premium over the market price for your common shares.

ARC Finance Group, LLC (*ARC Finance Group*), which is owned and controlled by Ms. Tracey Hampton, owns more than one-third of our outstanding common shares and voting securities. As a consequence of its substantial stock ownership position, ARC Finance Group effectively holds the practical ability to elect a majority of our board of directors or to remove any director, and thereby control our management. ARC Finance Group also has the practical ability to control the outcome of corporate actions requiring shareholder approval, including mergers and other changes of corporate control, going private transactions, and other extraordinary transactions. ARC Finance Group actively evaluates potential modifications to our board of directors and management, and could make such modifications or wholesale changes at any time if deemed to be in the company s best interest.

The sale of a large amount of common shares held by our shareholders or our executive officers or directors, or the perception that such sales could occur, could depress the prevailing market prices for our shares.

There are a substantial number of common shares either currently outstanding or acquirable upon exercise of common share purchase options or warrants by our officers, directors and principal shareholders that may be freely sold on the public markets. Included in these holdings are 3,500,000 common shares (out of a total of approximately 22,605,800 common shares) held by our controlling shareholder, ARC Finance Group, that we registered for sale in mid-2005 to provide ARC Finance Group with a mechanism to sell such shares on the public market should it decide to do so in view of its apparent ineligibility to sell those shares under the Rule 144 safe harbor under current SEC interpretations. Shortly after such registration, ARC Finance Group transferred a substantial portion of these shares to independent trustees under blind trusts it has established. As of this date neither ARC Finance Group nor Signalife knows if the independent trustees have sold any of such shares or, in the alternative, increased their position. ARC Finance Group reserves the right to sell the balance of the registered 3,500,000 common shares under 10b-5 plans or otherwise, although to our knowledge it has not, to date, sold those shares. We also regularly issue registered common shares to officers, employees, directors and certain eligible consultants as compensation for the provision of services, which are immediately available for sale. A large number of our shares, both registered and unregistered, may also be sold under available resale exemptions under the federal securities laws, including Rule 144 (albeit subject to volume limitations in the case of shares held by affiliates or restricted stock held for less than two years). We anticipate that a substantial number of the aforesaid registered and unregistered shares, whether currently held or acquired in the future by way of grant or exercise of common share purchase options or warrants, will be sold on the public markets for a number of reasons, including the need to satisfy income tax liabilities, the need to cover the purchase price of option and warrant exercises, or decisions predicated on market conditions. The occurrence of such sales, or the perception that such sales could occur, could depress the prevailing market prices for our shares.

A large number of common shares are issuable upon the exercise of outstanding common share purchase options or warrants. The exercise of these securities could result in the substantial dilution of your investment in terms of your percentage ownership in the company as well as the book value of your common shares. The sale of a large amount of common shares received upon the exercise of these securities on the

public market to finance the exercise price or to pay associated income taxes, or the perception that such sales could occur, could depress the prevailing market prices for our shares.

There are currently outstanding as of September 6, 2007, share purchase options and warrants entitling the holders to purchase 10,142,586 common shares at weighted average exercise prices of $2.20 per share. Included in these share purchase options are a large number granted to directors, officers, employees and consultants that are subject to vesting conditions. In the event of the exercise of these securities, you could suffer substantial dilution of your investment in terms of your percentage ownership in the company as well as the book value of your common shares. In addition, the holders of the common share purchase options or warrants may sell common shares in tandem with their exercise of those options or warrants to finance that exercise, or may resell the shares purchased in order to cover any income tax liabilities that may arise from their conversion or exercise of these securities.

Our issuance of additional common shares or preferred shares, or options or warrants to purchase those shares, would dilute your proportionate ownership and voting rights. Our issuance of additional preferred shares, or options or warrants to purchase those shares, could negatively impact the value of your investment in our common shares as the result of preferential voting rights or veto powers, dividend rights, disproportionate rights to appoint directors to our board, conversion rights, redemption rights and liquidation provisions granted to the preferred shareholders, including the grant of rights that could discourage or prevent the distribution of dividends to you, or prevent the sale of our assets or a potential takeover of our company that might otherwise result in you receiving a distribution or a premium over the market price for your common shares.

We are entitled under our certificate of incorporation to issue up to 100,000,000 common and 10,000,000 blank check preferred shares. After taking into consideration our common and series A preferred shares outstanding or accrued for issuance as of September 6, 2007, we will be entitled to issue up to 48,218,462 additional common shares and 9,985,453 additional preferred shares. Our board may generally issue those common and preferred shares, or options or warrants to purchase those shares, without further approval by our shareholders based upon such factors as our board of directors may deem relevant at that time. Any preferred shares we may issues shall have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. We cannot give you any assurance that we will not issue additional common or preferred shares, or options or warrants to purchase those shares, under circumstances we may deem appropriate at the time.

We are subject to the Delaware Business Combination Act, which could discourage or prevent a potential takeover of our company that might otherwise result in you receiving a premium over the market price for your common shares.

As a Delaware corporation, we are subject to the Delaware Business Combination Act which precludes a shareholder who owns 15% or more of our shares from entering into a business combination involving our company for a period of three years, unless (1) our board of directors approves the combination before the shareholder acquires the 15% interest; (2) the interested shareholder acquires at least 85% of our shares as part of the transaction in which he acquired the initial 15%, excluding shares owned by our

officers who are also directors and voting stock held by employee benefit plans; or (3) the combination is approved by a majority vote of our board of directors and two-thirds vote of our other shareholders at a duly called shareholders meeting. A business combination is defined as (1) a merger or consolidation requiring shareholder approval, (2) the sale, lease, pledge, or other disposition of our assets, including by dissolution, having at least 50% of the entire asset value of our company, or (3) a proposed tender or exchange offer of 50% or more of our voting stock.

The elimination of monetary liability against our directors, officers and employees under our certificate of incorporation and the existence of indemnification rights to our directors, officers and employees may result in substantial expenditures by our company and may discourage lawsuits against our directors, officers and employees.

Our certificate of incorporation contains provisions which eliminate the liability of our directors for monetary damages to our company and shareholders to the maximum extent permitted under Delaware corporate law. Our bylaws also require us to indemnify our directors to the maximum extent permitted by Delaware corporate law. We may also have contractual indemnification obligations under our agreements with our directors, officers and employees. The foregoing indemnification obligations could result in our company incurring substantial expenditures to cover the cost of settlement or damage awards against directors, officers and employees, which we may be unable to recoup. These provisions and resultant costs may also discourage our company from bringing a lawsuit against directors, officers and employees for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our shareholders against our directors, officers and employees even though such actions, if successful, might otherwise benefit our company and shareholders.

FORWARD-LOOKING STATEMENTS

In this prospectus 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) 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 other risks and uncertainties discussed in greater detail in the sections of this prospectus, including those captioned *Risk Factors* and *Management s Discussion And Analysis Of Financial Condition And Results Of Operations*.

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 prospectus as well as other public 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 prospectus to reflect new events or circumstances unless and to the extent required by applicable law.

USE OF PROCEEDS

The proceeds from the sale of the common shares to be sold under this prospectus will be retained by the selling shareholders, and will not be paid or remitted or otherwise made available to our company.

Included in the common shares offered for sale under this prospectus, are 1,500,000 common shares issuable upon the exercise of common share purchase warrants. These warrants contain cashless exercise provisions to the extent the sale of the underlying shares are not subject to an effective registration statement or in the event of an event of default as defined in the underlying Securities Purchase Agreement. In the event that the selling shareholders exercise any or all of these warrants for cash, we would be entitled to such cash proceeds.

BUSINESS

Overview

Signalife, Inc. 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, the Signalife *Fidelity 100 Monitor System* or *Fidelity 100* , is a heart monitoring systems that uses our proprietary Model 100 patient module to acquire, amplify and process physiological signals associated with a patient s cardiovascular system. Heart monitor systems are used in a variety of medical settings. For example, they are used to collect physiological data for electrocardiogram or ECG tests for the purpose of detecting and identifying cardiovascular disease, and also used to monitor the condition of the heart during surgical procedures. Our patient module operates using our proprietary patented signal acquisition and amplification technology, 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. Our proprietary signal acquisition and amplification technology provides the capability to collect, enlarge and process physiological signals in a manner that discriminates them from ambient or background electromagnetic noise, thereby facilitating the examination of the signal data for diagnostic purposes.

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 prospectus 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 our proprietary patented signal acquisition and 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. The principal use of heart monitor systems is to collect physiological data for electrocardiogram or ECG tests for the purpose of detecting and identifying cardiovascular disease. Other uses include the monitoring of the heart during surgical procedures. 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 or periodic basis for typically older patients as part of their annual or regular 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 in the low-activity states where a standard clinical or resting ECG is typically taken. 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 and the technical limitations of the algorithms used in the software, and cardiologists are therefore advised to look at the raw data and not to rely solely upon software-processed data.

Description Model 100 Patient Module

The core component of our heart monitoring systems is our battery-operated, digital 12-lead Model 100 patient module (the *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.

Description Of Products

Fidelity 100 Monitor System

Our initial product using the Model 100 Module is the Signalife *Fidelity 100 Monitor System* or *Fidelity 100* . The *Fidelity 100* 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.

The *Fidelity 100 Monitor System* is marketed 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. This product has received FDA 510(k) clearance as a class II medical device.

The *Fidelity 100 Monitor System* is principally used for clinical (resting) settings, including (1) monitoring the performance of the heart during surgical procedures including heart surgery; (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; and (3) as part of regular examinations or preventative programs for the purpose of detecting and identifying cardiovascular disease.

We introduced 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. Nevertheless, our marketing efforts for this product within the United States have been nominal to date, principally due to third-party performance issues in distributing our products while prior management devoted its limited time and resources to other matters. We are now focusing our efforts on formally launching this product into the United States market using our own resources.

Fidelity 200 Event Recording System

The Signalife *Fidelity 200 Event Recording System* or *Fidelity 200*, which is in the final development stage as discussed below, is a direct-to-consumer non-prescription credit card-sized heart monitoring device which has been specifically designed to be used in conjunction with monitoring centers. The *Fidelity 200*, which utilizes the proprietary physiological signal acquisition and amplification technology used in the *Model 100 Module*, will be used as an early-detection device by patients who desire to independently monitor their condition. Specifically, at the onset of an event that will be recorded, the 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. The patient will then either take the recorder to his or her physician for review or transmit the data to a subscription-based 24-hour monitoring center via a telephone phone line. In the latter case, the patient will call the monitoring center and upon verbal communication with receiving station personnel, position the monitor over the telephone mouthpiece, and start the transmission by pressing the play button. Data will then be transmitted to the monitoring center where it can be immediately evaluated by a qualified ECG technician, cardiac nurse or cardiologist.

We anticipate that we will sell the *Fidelity 200* to consumers through retail outlets such as drug stores, retail pharmacies, and major retail discount chains. The consumer will then separately subscribe to a monitoring services that is compatible with the device. We have applied for FDA 510(k) clearance for this product as a class II medical device, and anticipate we will receive clearance shortly. We anticipate that the production version will be completed by the end of fiscal 2007. We are currently in negotiations with several established monitoring centers in connection with pooling our efforts on the use and sale of the *Fidelity 200* for those centers and the sharing of subscription fees.

Fidelity 300 Holter Monitor

The Signalife *Fidelity 300 Holder Monitor* or *Fidelity 300*, which contains the proprietary physiological signal acquisition and amplification technology used in the *Model 100 Module*, is a three-lead ambulatory Holter device. The *Fidelity 300* is used while the patient carries out his or her daily activities away from the physicians office or hospital to collect ECG data relating to arrhythmia and other transient heart disease. Specifically, the data is acquired, processed, amplified and stored in a computer storage chip contained in the *Fidelity 300*, and then downloaded by the physician at a later date when the patient returns to the physician s office. The Fidelity 300 will allow up to thirty days of data to be recorded, satisfying physician needs for a more extensive database, unlike other holter markets currently on the market that record only for a period of 24 to 48 hours.

A major industry partner has indicated its desire to provide the software to be used with this product to scan the processed data, in conjunction with tests to be conducted through the Cleveland Clinic Heart Center. We have extended a right of first negotiation to that industry partner to distribute the *Fidelity 300*

on an OEM basis, and are in the process of documenting the anticipated testing regime. We are also in negotiations with another industry partner relating to a joint venture or distribution arrangement. Although we received FDA 5120(k) clearance for an earlier version of this prototype as a class II medical device, we intend to procure additional clearance given new features we have added. We anticipate that we would commence marketing the *Fidelity 300* by the end of fiscal 2007. We have extended a right of first negotiation to the aforesaid major industry partner to distribute the *Fidelity 300* on an OEM basis, and are in negotiations with another industry partner relating to a potential joint venture or distribution arrangement.

Fidelity 400 Intracardiac Monitor

The Signalife *Fidelity 400 Intracardiac Monitor* or *Fidelity 400* 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 a 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.

We developed and 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. We are in the process of planning a series of clinical studies through the Cleveland Clinic for the purposes of procuring FDA 510(k) clearance of the proto-type as a class II medical device. We are also currently designing, engineering and fabricating a production version of this product, which we anticipate will be completed and brought to market by the end of 2008 at the earliest. We are currently in discussion with several major industry partners relating to the commercialization and distribution of this product.

Cardiac Vest

In conjunction with the Champ Car World Series, the North America-based formula-one style auto racing circuit, and cardiologists from the Cleveland Clinic, 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*). 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. Cardiologists at the Cleveland Clinic 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 *Fidelity 100* using telemetry. It should be noted that in spite of extremely harsh and noisy testing conditions, we were able to precisely measure ECG signals using the *Cardiac Vest* and the *Fidelity 100*, demonstrating the efficacy of each.

We believe that the Signalife *Cardiac Vest* is more effective and convenient than the electrode/wire sets currently employed with ambulatory recording devices. When employing these electrode/wire sets, the intended attachment site requires proper shaving and preparation of the site and the use of gels to ensure

that the lead remains affixed to the site. If the electrode is dislodged from the location site by physical activity or lack of proper site preparation, the Holter monitor will not record the proper signal. In the case of the Signalife *Cardiac Vest,* the electrodes incorporated into the vest do not need to be attached to the skin. Instead, they need only remain adjacent to the proper location, which is effected through the design and materials used in the vest.

We have are currently designing, engineering and fabricating a production version of the Signalife *Cardiac Vest*, which we anticipate will be completed and brought to market by the end of fiscal 2008 at the earliest. We will also need to procure FDA 510(k) clearance for this product. We 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.

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 either uses an event recorder to independently monitor their condition, or wears a Holter monitor to record data over an extended period of time while performing his or her daily activities away from the physicians office or hospital. The data from the event recorder or Holter monitor is typically 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 or both of our *Fidelity 200 Event Recording System* or a telemetry-based version of the Signalife *Fidelity 300 Holter Monitor* in conjunction with our *Cardiac Vest*. At this point we are in discussions with several patient monitoring centers relating to a collaborative arrangement whereby the center would use the *Fidelity 200* and we would share subscription fees.

Description Of Products In Investigational Stage

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 prospectus, 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 2009 at the earliest, however, new management and board members at the company are actively re-evaluating this stratagem.

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, 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 indicate that the *Fidelity 100 Monitor System* provides excellent detection and quantification of transient ischemia. A summary of the results were presented at the IEEE EMBC 2007 conference held in August 2007 in Lyon, France, and full clinical data will be released in the American Journal of Cardiology.

As previously discussed, we have also validated our beliefs as to the performance of our signal acquisition and amplification technology through the tests conducted by cardiologists at the Cleveland

Clinic successfully tested the vest during fiscal 2006 in the Champ Car Series pursuant to which we were able, in spite of harsh and noisy racing conditions, to precisely measure ECG signals.

Competitive Advantages And Marketing Strategy

As discussed above, 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. Signalife believes that this ability affords the *Fidelity 100* heart monitor with significant competitive advantages over the state-of-the-art heart monitors currently on the market. These advantages can be most easily demonstrated and explained by the following graphic, which compares two ECG print-outs taken during a cardiac surgical procedure (seen in the background) recently performed at a major hospital.

The readout on the left is from the *Fidelity 100* heart monitor, while the read-out on the right is from a state of the art heart monitor offered by a competitor. The *Fidelity 100* read out shows the waveform of the normal or proper heart function from all eight leads. The read-out from the state of the art monitor, on the other hand, shows only one lead (on the top) which has any similarity whatsoever to a normal waveform. The data from the second lead is confusing and essentially meaningless, although it could be construed to indicate that there are potentially heart problems, even though there is none indicated on the Signalife read-out. The other leads show no data whatsoever. The significance of the foregoing is that not only does the *Fidelity 100* monitor consistently give accurate signals from all leads in all cases, it also avoid false positives relating to inaccurate information. Specifically, since, as a practical matter, the meaning of the signal from the second lead on the state of the art monitor is meaningless, the physician can only speculate as to what is going on with the heart, and can potentially misdiagnose the condition of the heart.

The reason for the efficacy of the *Fidelity 100* heart monitor over state of the art heart monitors is fairly simple. The *Fidelity 100* has been designed to collect only the signals from the heart, while ignoring and not being confused by all the other electronic clutter that is occurring in the operating (or ambulatory) environment, including other physiological signals from the body (such as from the brain and other organs) and other electromagnetic signals from the numerous devices in the operating room or surrounding environment. In the case of the state of the art devices, they collect all of the data from the surrounding environment, both physiological and electromagnetic, and then attempt to filter out the other noise sources, with the results seen above. Specifically, much of the data is either distorted, confusing and potentially misleading (as in the case of lead 2), or omitted or non-existent (such as in the case of leads 3 to 8).

As a consequence, Signalife believes that hospitals and physicians will have a huge inducement to purchase the *Fidelity 100* they can more accurate monitor heart functions in all settings and under all conditions surgical, diagnostic, and ambulatory--and avoid misdiagnosis, leading to better patient results, eliminating liability. Moreover, this ability will allow them to eliminate other monitoring functions, thereby reducing procedure costs. Given that there is one heart attack in the United States every 34 seconds, Signalife believes that this enhanced ability to detect cardiac disease early and will lead to life-saving intervention.

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

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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 other clinical resting 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 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.

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

Our initial marketing efforts for the *Fidelity 100* since its introduction have been extremely limited to date principally due to performance issues with third-party distributors and sales agents to whom we originally delegated sales authority, our limited internal sales and marketing support functions and personnel, and the focus of prior management on other activities. We have recently launched a company-sponsored program to aggressively market and promote the *Fidelity 100* in the United States, in which we will rely upon new senior management and directors, consisting of Dr. Lowell T. Harmison, the President and Chief Operating Officer and a director of Signalife, and Drs. Steven J. Phillips, Robert E. Windom and Jay A. Johnson, directors of Signalife, taking the initiative to personally market the *Fidelity 100* to selected marquee cardiac hospitals in the United States and selected physicians and physician groups to whom they have pre-existing relationships and entrees to top management and decision makers. Given their prominent reputations in the industry, Signalife believes Drs. Harmison, Phillips, Windom and Johnson will be able to cut through red-tape to more quickly demonstrate the benefits of the product and procure purchase orders, thereby in kick-starting sales and achieving market acceptance of the *Fidelity 100* heart monitor as the state of the art heart monitor. Given that Drs. Harmison, Phillips, Windom and Johnson and have extensive experience in one or more different but complementary medical areas that will use the Signalife *Fidelity 100* heart monitor for slightly different purposes and benefits cardiology, internal medicine, and cardiac surgery Signalife will have the ability to better address physician concerns in each such area.

Signalife also intends to develop its own internal sales team, and will likely engage independent commissioned salespersons or joint venture partners to distribute our products in the United States under certain circumstances. New management is currently reevaluating the company`s existing independent sales agents in view of prior performance issues. 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 internationally (principally Mexico to date) and the United States, and to otherwise generate product awareness.

We are also in discussions with several prospective industry partners relative to distributing our products, including an the *Fidelity 100 Monitor System*; the Signalife *Fidelity 200 Event Recording System*; the

Fidelity 300 Holter Monitor, the *Fidelity 400 Intracardiac Monitor*, 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 a national gym, in which patrons of the gym at a selected facility were tested using the Signalife *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 previously budgeted $1,711,000 for research and development for fiscal 2007, although this forecast is currently under review and most likely will be changed.

Regulatory Overview

Current Status

Our heart monitors are Class II medical devices that must be cleared by the FDA in order to be marketed within the United States. We have, to date, received FDA 510(k) clearance under the FDA s abbreviated 510(k) submission

format allowing us to market our Model 100 Module as a class II medical device 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. We are awaiting 510(k) clearance for the *Fidelity 200* Event

Recorder. Under the terms of the abbreviated 510(k) clearance, we are required to have supporting data in our files documenting that the heart monitoring device/system will conform to performance standards before it can be marketed. As such, we may continue to perform engineering and design work on the heart monitoring device/system 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.