SPO Medical Inc
Form 10KSB
March 20, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

MARK ONE:

x **ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934** for the Fiscal Year ended December 31, 2006

o **TRANSITION REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIESEXCHANGE ACT OF 1934**

COMMISSION FILE NUMBER: 0-11772

SPO MEDICAL INC.
(Exact name of Small Business Issuer as specified in its chapter)

Delaware	11-3223672
(State or Other Jurisdiction of Incorporation)	(IRS Employer Identification No.)

21860 Burbank Blvd., North Building, Suite 380, Woodland Hills, CA 91367
(Address of Principal Executive Offices)

818-888-4380
(Small Business Issuer's Telephone Number, including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: None

Securities Registered Pursuant to Section 12(g) of the Exchange Act: $0.01 Par Value Common Stock

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. o

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Check if there is no disclosure contained herein of delinquent filers in response to Item 405 of Regulation S-B, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The issuer's revenues for the year ended December 31, 2006: $3,714,000

As of March 16, 2007, there were 19,335,525 shares of the issuer's common stock outstanding. The aggregate market value of the shares of the issuer's common stock held by non-affiliates was approximately $28 million based on the last reported sale price of $1.89 per share on March 15, 2007 as quoted on the Pink Sheets. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not a determination for other purposes.

Transitional Small Business Disclosure Format (Check one): Yes o No x

SPO MEDICAL INC.
2006 FORM 10-KSB ANNUAL REPORT

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FORWARD LOOKING STATEMENTS

CERTAIN STATEMENTS MADE IN THIS ANNUAL REPORT ON FORM 10-KSB ARE "FORWARD-LOOKING STATEMENTS" WITHIN THE MEANING OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995. FORWARD-LOOKING STATEMENTS CAN BE IDENTIFIED BY TERMINOLOGY SUCH AS "MAY", "WILL", "SHOULD", "EXPECTS", "INTENDS", "ANTICIPATES", "BELIEVES", "ESTIMATES", "PREDICTS", OR "CONTINUE" OR THE NEGATIVE OF THESE TERMS OR OTHER COMPARABLE TERMINOLOGY. BECAUSE FORWARD-LOOKING STATEMENTS INVOLVE RISKS AND UNCERTAINTIES, THERE ARE IMPORTANT FACTORS THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED BY THESE FORWARD-LOOKING STATEMENTS. ALTHOUGH THE COMPANY BELIEVES THAT EXPECTATIONS REFLECTED IN THE FORWARD-LOOKING STATEMENTS ARE REASONABLE, IT CANNOT GUARANTEE FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS. MOREOVER, NEITHER THE COMPANY NOR ANY OTHER PERSON ASSUMES RESPONSIBILITY FOR THE ACCURACY AND COMPLETENESS OF THESE FORWARD-LOOKING STATEMENTS. THE COMPANY IS UNDER NO DUTY TO UPDATE ANY FORWARD-LOOKING STATEMENTS AFTER THE DATE OF THIS REPORT TO CONFORM SUCH STATEMENTS TO ACTUAL RESULTS.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

History

SPO Medical Inc. was originally organized under the laws of the State of Delaware in September 1981 under the name "Applied DNA Systems, Inc." On November 16, 1994, the company changed its name to "Nu-Tech Bio-Med, Inc." and on December 23, 1998, its name was changed to "United Diagnostic, Inc." Effective April 21, 2005, we acquired (the "Acquisition Transaction") 100% of the outstanding capital stock of SPO Medical Equipment Ltd., a company incorporated under the laws of the State of Israel ("SPO Ltd."), pursuant to a Capital Stock Exchange Agreement dated as of February 28, 2005 among SPO Medical Inc., SPO Ltd. and the shareholders of SPO Ltd., as amended and restated on April 21, 2005. In exchange for the outstanding capital stock of SPO Ltd., we issued to the former shareholders of SPO Ltd. a total of 5,769,106 shares of its common stock, par value $0.01 per share ("Common Stock"), representing approximately 90% of the Common Stock then issued and outstanding after giving effect to the Acquisition Transaction. As a result of the Acquisition Transaction, SPO Ltd. became our wholly owned subsidiary and we changed our name from United Diagnostic Inc. to "SPO Medical Inc." Upon consummation of the Acquisition Transaction, we effected a forward subdivision of our Common Stock issued and outstanding on a 2.65285:1 basis.

Following the Acquisition Transaction, we began to engage in the business that SPO Ltd. was engaged in.

Business Overview

Since its incorporation in August 1995, SPO Ltd. has been engaged in the design, development and marketing of non-invasive pulse oximetry technologies to monitor blood oxygen saturation and heart rate for a variety of markets, including medical, homecare, sports and search & rescue. Pulse oximetry is a non-invasive process used to measure blood oxygen saturation levels and is an established procedure in medical practice.

We utilize proprietary and patented technologies to deliver oximetry functionality through innovative commercial products that address such applications as emergency care, home monitoring, sleep apnea, cardiovascular performance, cardiac rehabilitation and the physiological monitoring of military personnel and safety care workers.

We have developed and patented proprietary technology that enables the use of pulse oximetry in a reflectance mode of operation (i.e. a sensor that can be affixed to a single side of a body part). This technique is known as Reflectance Pulse Oximetry (RPO). Using RPO, a sensor can be positioned on various body parts, hence minimizing problems of motion and poor profusion. The unique design features contribute to substantially lower electric power requirements and enable a wireless, stand-alone configuration with expanded commercial possibilities.

Background

Pulse oximetry is an important non-invasive process used to both measure blood oxygen saturation levels (SpO2) by monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen and measure heart rate. This procedure has been used regularly in hospitals during the past twenty years and is established as an essential measurement in medical practice to ensure maintenance of adequate oxygen and prevention of respiratory difficulty. In many disease states, oxygen saturation is one of the most important vital signs to monitor.

There are two methods to measure pulse oximetry by transmission through a body part or by reflection. In general, the transmission method can only be used on certain areas of the body, such as fingers, earlobes, etc. Furthermore, in some instances when the transmission method is used, physiological conditions such as stress and temperature can adversely affect the accuracy of pulse oximetry readings.

Since pulse oximetry measurements taken on-site in an emergency, at local medical practices, and/or in home care can save lives and curtail intervention costs, mobile units have been developed. However, mobile oximetry units have not been widely adopted because their power requirements (and hence limited battery life) often make them impractical. In addition, existing mobile units require patients to remain absolutely stationary to produce reliable results, further reducing their practicality.

Our solution

Responding to the need for life-saving information in the field where people cannot be absolutely stationary, we have developed patented sensors that work accurately during mild physical activity. This technique uses a reflectance method (known as RPO) whereby a very small sensor placed on the body at various locations has the ability to measure oxygen saturation and heart pulse rate. We have incorporated our patented reflectance technology into portable devices for medical and consumer applications. Moreover, these devices operate at a power requirement approximately 1/50th of that compared to other commercially available portable systems. This puts pulse oximetry into the hands medical practitioners and emergency personnel on-site for the safety and benefit of all and offers the opportunity to create new commercial and consumer applications.

We intend to leverage our core technologies to develop new, innovative product applications. For instance, we are currently investigating monitoring of other vital sign information that can be obtained using other optical, non-invasive techniques including :

- Blood pressure using reflectance oximetry
- Billirubin levels
- Monitoring glucose levels in blood
- Hemoglobin count in blood

Products

The following details our products utilizing our unique pulse oximetry technology.

PulseOx 5500TM -- a stand-alone commercial RPO spot check monitor for SpO2 and heart rate. The PulseOx 5500TM uses SPO patented technology to provide a medical device which is easier to use for many patients and less expensive to operate than any other device that is commercially available. Its main advantages include: (i) long lasting battery with more than 1,000 hours, using only a fraction of the power used by competitive devices and (ii) resistance to many forms of motion, reducing its susceptibility to the motion artifacts which are typical of other pulse oximetry devices. The PulseOx 5500 was first introduced commercially during the fourth quarter of 2004. The device was approved and registered by the Food and Drug Administration ("FDA") in June 2004. The device also carries the CE (European Directives 93/42/EEC and 90/385/EEC for regulatory and safety standards of medical equipment) and Canadian Standards Association (CSA) mark for safety and audited manufacturing processes, all of which were obtained in February 2005.

Check MateTM--- addresses the sports and aviation market's demand for a lightweight, inexpensive monitor for measuring SpO2 and heart rate during physically active and high-altitude activities. It offers the user a greater ability to monitor these vital signs under motion and is less expensive than most other available devices. The Check Mate was first introduced commercially during third quarter of 2005. The Check Mate does not require FDA approval or registration. It carries the CE and CSA mark for safety and audited manufacturing processes.

PulseOx 7500TM --a monitor for extended monitoring of SpO2 and heart rate by means of RPO. The monitor is being initially marketed for pre screening of sleep apnea sufferers. Our monitor's main advantages include: (i) long lasting battery equivalent to a month's use of monitoring using only a fraction of the power used by competitive devicesand hence a lower cost of ownership and (ii) resistance to many forms of motion, reducing its susceptibility to the motion artifacts which are typical of other similar pulse oximetry devices.

Research & Development / Products Under Design and Development

We currently have in various stages of development other devices utilizing its oximetry technology. These include the following:

Handheld -- a stand-alone commercial RPO spot check monitor for SpO2 and heart rate. The Handheld will use our patented technology to provide a medical device which is easier to use and have lower operating costs than other devices currently widely used in hospitals and related environments. The device's main advantages are expected to include: (i) long lasting battery with more than 1,000 hours, using only a fraction of the power used by competitive devices and (ii) resistance to many forms of motion, reducing its susceptibility to the motion artifacts which are typical of other pulse oximetry devices

PedOMetrixTM -- a monitor being designed specifically for the use with infants. This unique monitor is being designed for continual non-invasive monitoring of an infant.

Our research and development activities as well as product design activities are primarily conducted in our research and development subsidiary SPO Ltd. located in Israel. During our 2006 and 2005 fiscal years, we expended approximately $972,000 and $629,000, respectively, on the research and development.

Business Strategy

Our mission is to build a profitable business that develops and commercializes medical biosensor products that improve people's lives and increases stockholder value. To achieve this mission, we are pursuing the following business strategies:

* Establish our brand in both the medical and consumer marketplaces. The initial product launch PulseOx 5500TM was a demonstration of our strategy to establish our company within the most demanding part of the market - medical devices requiring FDA approval and requiring a doctor's prescription. Thereafter, subject to regulatory approval consumer applications using the technology will be marketed for direct purchase at appropriate outlets (e.g., retail drug chains, sports and fitness establishments, distributors of safety and security products).

* Partner with highly qualified, focused companies, internationally. We intend to collaborate with leading medical device resellers capable of distributing the products to the target market. For instance, we currently sell the PulseOx 5500(TM) through reputable, established medical device distributors serving North American markets and the European, Asian and Latin American markets. Other medical products may be distributed by these and other distributors. We anticipate that our other consumer products, such as the Check Mate(TM), will be distributed by companies with access to its target market which includes sports enthusiasts. Finally, with medical and consumer products developed jointly with other companies, the most appropriate distribution channels will be used for each product and application.

* Research and Development. Our research and development strategy is to continually improve and expand our product offerings by leveraging existing and newly developed proprietary technologies, as well as those of our collaborators, into new product offerings. We intend to pursue a multi-disciplinary approach to product design that includes substantial electrical, mechanical, software and biomedical engineering efforts. We are currently focusing research and development programs on expanding our current product offering and investigations in to other non-invasive optical techniques for blood analysis of other vital signs in blood. In addition, we have established relationships with leading teaching hospitals and academic institutions for the purpose of clinically evaluating its new products. We have consulting arrangements with physicians and scientists in the areas of research, product development and clinical evaluation.

Suppliers

Our products are made of components which we manufacture or which are usually available from existing and alternate sources of supply. Some of our products are manufactured through agreements with unaffiliated companies. We purchase certain components from single or preferred sources of supply. The use of single or preferred sources of supply increases our exposure to price increases and production delays.

We outsource our primary manufacturing operations. We utilize contract manufacturers that are ISO 13485:2003 certified. However, the outsourcing of these operations may mean that some degree of risks related to delivery schedules, yields, and other factors are not directly under our control.

Marketing and Sales Organization

Our products are sold primarily through resellers in the United States and a combination of resellers and independent distributors in international markets. Our primary markets include home care, physicians, hospitals, other medical institutions and general home-care providers.

We provide service and maintenance to purchasers of our products under warranty. We employ service representatives in the United States and Europe and maintain service facilities in the United States and through our resellers in Europe and elsewhere.

Patents and Proprietary Information

We currently rely on a combination of patent, trade secret, copyright and trademark law, as well as non-disclosure agreements and invention assignment agreements, to protect proprietary information. However, such methods may not afford complete protection and there can be no assurance that other competitors will not independently develop such processes, concepts, ideas and documentation. We hold three patents issued by the United States Patent and Trademark Office ("USPTO") covering various aspects of our unique sensors for radiance based diagnostics using pulse oximetry. Although we believe that our existing issued patents provide a competitive advantage, there can be no assurance that the scope of our patent protection is or will be adequate to protect our technologies or that the validity of any patent issued will be upheld in the future.

Because of the uncertainty of patent protection and the unavailability of patent protection for certain processes and techniques, our policy is to require our employees, consultants, other advisors, as well as utility and design collaborators, to execute confidentiality and assignment of invention agreements upon the commencement of employment, consulting or advisory relationships. These agreements generally provide that all confidential information developed or made known to a party by us during the course of the party's association with the Company is to be kept confidential and not to be disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements also provide that all inventions conceived by the individual in the course of their employment or consulting relationship will be our exclusive property.

Employees

As of March 16, 2007, we employed 22 full-time employees, of which four work out of our corporate offices in California and 18 out of facilities in Israel. None of these employees is subject to collective bargaining agreements.

Competition

We believe that hospitals and other medical institutions choose among competing products on the basis of product performance, features, price and service. In general, we believe that price has become an important factor in hospital purchasing decisions because of pressure to cut costs. These pressures on hospitals result from federal and state regulations that limit reimbursement for services provided to Medicare and Medicaid patients. There are also cost containment pressures on healthcare systems outside the U.S.A., particularly in certain European countries.

There are number companies, some of which are substantially larger than we are and with significantly more resources, are engaged in manufacturing competing products. Our competition is primarily in the traditional medical market. Our competitors include Nellcor, a unit of the Tyco Healthcare division of Tyco International Ltd; Nonin Medical Inc. of Plymouth, Minnesota, a privately owned company; and Smiths Medical PM Inc. of Waukesha, WI, which is the designer, manufacturer, and distributor of the BCI(R) brand of patient monitoring equipment which competes with the SPO PulseOx 5500TM units.

Governmental Regulations

The manufacture and sale of our products are subject to extensive regulation by numerous governmental authorities, principally by the FDA and corresponding foreign agencies. The FDA administers the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder. Our PulseOx 5500TM and PulseOx 7500TM are sold in

the United States and are subject to the FDA's standards and procedures for the manufacture of medical devices and our facilities are subject to inspection by the FDA for compliance with such standards and procedures.

The FDA classifies each medical device into one of three classes depending on the degree of risk associated with the device and the extent of control needed to ensure safety and effectiveness. The Company's PulseOx 5500TM and the PulseOx 7500TM have been classified by the FDA as Class II device and has secured a 510(k) pre-market notification clearance before being introduced into the United States market. For additional products, the process of obtaining 510(k) clearance typically takes several months and may involve the submission of limited clinical data supporting assertions that the product is substantially equivalent to an already approved device or to a device that was on the market before the enactment of the Medical Device Amendments of 1976.

Every company that manufactures or assembles medical devices to be sold in the United States is required to register with the FDA and adhere to certain "good manufacturing practices" in accordance with the FDA's Quality System Regulation which regulates the manufacture of medical devices, prescribes record keeping procedures and provides for the routine inspection of

facilities for compliance with such regulations. The FDA also has broad regulatory powers in the areas of clinical testing, marketing and advertising of medical devices.

Medical device manufacturers are routinely subject to periodic inspections by the FDA. If the FDA believes that a company may not be operating in compliance with applicable laws and regulations, it can:

- place the company under observation and re-inspect the facilities; o issue a warning letter apprising of violating conduct;
- detain or seize products;
- mandate a recall;
- enjoin future violations; and
- assess civil and criminal penalties against the company, its officers or its employees.

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in such countries are similar to those of the FDA. The national health or social security organizations of certain countries require our products to be qualified before they can be marketed in those countries.

AVAILABLE INFORMATION

Our Internet website is located at http://www.spomedical.com. This reference to our Internet website does not constitute incorporation by reference in this report of the information contained on or hyperlinked from our Internet website and such information should not be considered part of this report.

The public may read and copy any materials we file with the Securities and Exchange Commission ("SEC") at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The SEC's Internet website is located at http://www.sec.gov.

Risk Factors

The following risk factors should be considered carefully in addition to the other information presented in this report. This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, the following:

WE HAVE A HISTORY OF LOSSES AND EXPECT TO INCUR LOSSES AND NEGATIVE OPERATING CASH FLOWS IN THE FUTURE.

Our accumulated deficit was approximately $11,049,000 as at December 31, 2006. We expect our operating losses to continue as we continue to expend resources to further develop and enhance our existing product lines, to complete development of new generation products, obtain regulatory clearances or approvals, expand our marketing, sales, manufacturing and finance capabilities and conduct further research and development.

We also expect to experience negative cash flow in the future as we fund our operating losses and capital expenditures. We currently have three products that are commercially available. In order to achieve and maintain profitability we must expand our existing product lines.

WE MAY NEED TO RAISE ADDITIONAL FUNDS TO IMPLEMENT OUR BUSINESS PLAN AND THERE IS NO ASSURANCE THAT SUCH FUNDS CAN BE RAISED ON TERMS THAT WE WOULD FIND ACCEPTABLE, OR AT ALL.

Although management believes funds on hand as well as revenues that we expect to generate in the ordinary course of our business may enable us to meet our operating liquidity needs as they arise, circumstances may arise that would require us to raise additional capital in order to meet our liquidity needs and satisfy our current business plan. We do not know whether additional financing will be available when needed, or on terms favorable to our stockholders or us. We may raise any necessary funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. Any

failure to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of one or more of our development initiatives. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited. Any additional equity financing may be dilutive to stockholders, and debt and certain types of equity financing, if available, may involve restrictive covenants or other provisions that would limit how we conduct our business or finance our operations.

WE ARE CURRENTLY DEPENDENT ON LIMITED NUMBER OF PRODUCTS AND IN ORDER TO SUCCEED WE WILL NEED TO DEVELOP AND COMMERCIALIZE OTHER PRODUCTS CURRENTLY UNDER DEVELOPMENT.

Unlike many of our competitors which have commercialized a number of products, we are currently dependent on our three pulse oximetry products for the generation of revenues. The PulseOx 5500 was first commercially available in the fourth quarter of 2004. While our core technology has a number of potentially beneficial uses, if that core technology is not widely accepted in the marketplace, we currently do not have other commercialized products to fall back on.

We began commercial distribution of the PulseOx 7500TM first quarter 2007. Commercial distribution of the PedOMetrixTM, a monitor being designed specifically for the use with infants and also currently under development, is expected to commence during late fourth quarter of 2007. However, potential products that appear to be promising at any development stage may not reach the market for a number of reasons. These reasons include the possibility that the potential products may:

* be found ineffective or cause harmful side effects;

* fail to receive necessary regulatory approvals;

* be precluded from commercialization by proprietary rights of third parties;

* be difficult to manufacture on a large scale; or

* be uneconomical or fail to achieve market acceptance.

If any of these potential problems occur, we may not successfully market these products.

WE DO NOT HAVE A LONG OPERATING HISTORY, WHICH MAKES IT DIFFICULT FOR YOU TO EVALUATE OUR BUSINESS.

SPO Ltd. commenced operations in 1998. We introduced our first product into the marketplace in the fourth quarter of 2004. Accordingly, there is limited historical information regarding our revenue trends and operations upon which investors can evaluate our business. Our prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasing intense competition and the relative failure rates.

THE SALE OF OUR PRODUCTS IN THE UNITED STATES IS SUBJECT TO GOVERNMENT REGULATIONS AND WE MAY NOT BE ABLE TO OBTAIN CERTAIN NECESSARY CLEARANCES OR APPROVALS.

The design, manufacturing, labeling, distribution and marketing of medical device products in the United States is subject to extensive and rigorous regulation by the Food and Drug Administration (FDA). In order for us to market our products in the United States, we must obtain clearance or approval from the FDA. which can be expensive and

uncertain and can cause lengthy delays before we can begin selling our products. We cannot be sure:

- that we, or any collaborative partner, will make timely filings with the FDA;
- that the FDA will act favorably or quickly on these submissions;
- that we will not be required to submit additional information or perform additional clinical studies;
- that we would not be required to submit an application for pre-market approval, rather than a 510(k) pre-market notification submission as described below; or
- that other significant difficulties and costs will not be encountered to obtain FDA clearance or approval.

The FDA may impose strict labeling or other requirements as a condition of its clearance or approval, any of which could limit our ability to market our products. Further, if we wish to modify a product after FDA clearance of a pre-market notification or approval of a pre-market approval application, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals will be required from the FDA. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies or submit to the more rigorous and lengthier pre-market approval process, could result in a significant delay in bringing our products to market and substantial additional research and other expenditures. Similarly, any labeling or other conditions or restrictions imposed by the FDA on the marketing of our products could hinder our ability to effectively market our products. Any of the above actions by the FDA could delay or prevent altogether our ability to market and distribute our products. Further, there may be new FDA policies or changes in FDA policies that could be adverse to us.

OUTSIDE THE UNITED STATES, WE ARE SUBJECT TO GOVERNMENT REGULATION, WHICH COULD DELAY OR PREVENT OUR ABILITY TO SELL OUR PRODUCTS IN CERTAIN JURISDICTIONS.

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required to market our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country.

EVEN IF WE OBTAIN CLEARANCE OR APPROVAL TO SELL OUR PRODUCTS, WE ARE SUBJECT TO ONGOING REQUIREMENTS AND INSPECTIONS THAT COULD LEAD TO THE RESTRICTION, SUSPENSION OR REVOCATION OF OUR CLEARANCE.

We are required to adhere to applicable FDA regulations and ISO standards regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements will be strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable Notified Body for CE Marking and ISO Standards. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

OUR SUCCESS LARGELY DEPENDS ON OUR ABILITY TO OBTAIN AND PROTECT THE PROPRIETARY INFORMATION ON WHICH WE BASE OUR PRODUCTS.

Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others patents and patent applications necessary to develop our products. If any of our patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our products was to be limited, our ability to continue to manufacture and market our products could be adversely affected.

The defense of patent infringement suits is costly and time-consuming and their outcome is uncertain. An adverse determination in litigation could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes are often settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, the necessary licenses may not be available to us on satisfactory terms, if at all. Thus, as discussed above, if third party patents cover any aspect of our products or processes, then we may lack freedom to operate in accordance with our business plan.

We have been issued three United States patents. One or more of the patents for our existing or future products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that

prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the United States Patent and Trademark Office may institute interference proceedings. The defense and prosecution of intellectual property suits, Patent and Trademark Office proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the proceedings could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from selling our products in some or all markets. We may not be able to reach a satisfactory settlement of any dispute by licensing necessary patents or other intellectual property. Even if we reached a settlement, the settlement process may be expensive and time consuming, and the terms of the settlement may require us to pay substantial royalties. An adverse determination in a judicial or administrative proceeding or the failure to obtain a necessary license could prevent us from manufacturing and selling our products.

In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

Finally, our PulseOx 7500TM utilizes third party owned proprietary licensed software. If for, whatever reason, we are unable to maintain the license or renew it on commercially acceptable terms (or at all) or if such party’s right to such proprietary rights are challenged and we are unable to maintain these licenses or obtain or develop replacement technologies, our business may be adversely affected.

WE ARE DEVELOPING OUR CURRENT PRODUCT LINES INDEPENDENTLY FROM ANY COLLABORATIVE PARTNERS, WHICH WILL REQUIRE US TO ACCESS ADDITIONAL CAPITAL AND TO DEVELOP ADDITIONAL SKILLS TO PRODUCE, MARKET AND DISTRIBUTE THESE PRODUCTS.

We are independently finishing development, building up production capacity, launching, marketing and distributing our oximetry line of products. These activities require additional resources and skills that we will need to secure