BioElectronics Corp
Form SB-2/A
December 06, 2006

**As filed with the Securities and Exchange Commission on December 6, 2006**

**Registration No. 333- 136602**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM SB-2/A**

**(AMENDMENT NO. 3)**

**REGISTRATION STATEMENT**

**UNDER**

**THE SECURITIES ACT OF 1933**

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# BioElectronics Corporation

(Name of Small Business Issuer in Its Charter)

| **Maryland** (State or Other Jurisdiction of Incorporation or Organization) | **3845** (Primary Standard Industrial Classification Code Number) | **52-2278149** (I.R.S. Employer Identification No.) |
|---|---|---|

**401 Rosemont Avenue, 3rd Floor**

**Rosenstock Hall**

**Frederick, Maryland 21701**

**(301) 644-3906**

(Address and Telephone Number of Principal Executive Offices)

**Andrew J. Whelan, President**

**BioElectronics Corporation**
**4539 Metropolitan Court**

**Frederick, Maryland 21704**

**(301) 644-3906**

(Name, address and telephone number of agent for service)

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**Copies to:**

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Approximate Date of Commencement of Proposed Sale to the Public: From time to time after this Registration Statement becomes effective.

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, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box.

**CALCULATION OF REGISTRATION FEE**

| Title of Each Class of Securities To be Registered | Amount to be Registered | Proposed Maximum Aggregate Offering Price Per Share(1) | Proposed Maximum Aggregate Offering Price(1) | Amount of Registration Fee |
|---|---|---|---|---|
| Common Stock, $.001 par value (2) | 10,451,389 shares | $ 0.09 | $ 940,625.01 | $100.65 |
| Common Stock, $.001 par value (3) | 9,311,500 shares | $ 0.09 | $ 838,035.00 | $ 89.67 |
| Common Stock, $.001 par value (4) | 3,420,000 shares | $ 0.09 | $ 307,800.00 | $ 32.93 |
| Total Registration Fee (5) | 23,182,889 shares | _____ | $ 2,086,460.01 | $ 223.20 |

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(1)

Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) based on the average of the bid and asked prices on the Pink Sheets on December 5, 2006.

(2)

The shares of common stock being registered hereunder are being registered for resale by certain selling stockholders named in the prospectus upon conversion of outstanding secured convertible notes and include 166,667 shares for accrued interest and 250,000 shares for liquidated damages. In accordance with Rule 416(a), the registrant is also registering hereunder an indeterminate number of shares that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(3)

The shares of common stock being registered hereunder are being registered for resale by certain selling stockholders named in the prospectus upon exercise of outstanding two to five-year warrants. In accordance with Rule 416(a), the registrant is also registering hereunder an indeterminate number of shares that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(4)

The shares of common stock were issued in connection with the Private Placement Offering of the Company's common stock on April 4 2005.

(5) Previously paid.

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**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 the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

# Prospectus

# Subject to Completion, Dated December 6, 2006

# 23,182,889 Shares of Common Stock

## Makers of Drug Free, Anti-Inflammatory Patches

This prospectus relates to the resale of up to 23,182,889 shares of common stock (the "Common Stock"), of which 10,451,389 shares are issuable upon the conversion of promissory notes of BioElectronics Corporation (the "Company") and includes 166,667 shares for accrued interest and 249,999 shares for liquidated damages, 3,420,000 shares listed in connection with the Company's April 2005 Private Placement Offering, and 9,311,500 shares of Common Stock issuable upon the exercise of warrants of the Company by certain selling stockholders identified in this prospectus (the "Offering"). All of these shares, when sold, will be sold by these selling stockholders. The selling stockholders may sell their Common Stock from time to time at prevailing market prices. We will not receive any proceeds from the sale of the shares of Common Stock by the selling stockholders.

Bid and ask prices for our Common Stock are quoted from broker dealers on the Pink Sheets. The Company's symbol is "BIEL. OTC:PK."

*See "Risk Factors" beginning on page 7 for risks of an investment in the securities offered by this prospectus, which you should consider before you purchase any shares.*

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is _____, 2006

This prospectus is not an offer to sell any securities other than the shares of Common Stock offered hereby. This prospectus is not an offer to sell securities in any circumstances in which such an offer is unlawful.

We have not authorized anyone, including any salesperson or broker, to give oral or written information about this Offering, the Company, or the shares of Common Stock offered hereby that is different from the information included in this prospectus. You should not assume that the information in this prospectus, or any supplement to this prospectus, is accurate at any date other than the date indicated on the cover page of this prospectus or any supplement to it.

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**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this Prospectus and may not contain all of the information that you should consider before investing in the shares. You are urged to read this Prospectus in its entirety, including the information under "Risk Factors" and our financial statements and related notes included elsewhere in this Prospectus.*

**OUR COMPANY**

BioElectronics Corporation (the "BioElectronics", "us", "our", "we" or the "Company") is the maker of ActiPatch Therapy ("ActiPatch Therapy"), a microchip embedded into a disposable soft foam patch that delivers pulsed electromagnetic field therapy, a clinically proven and widely accepted anti-inflammatory and pain relief therapy, previously only available from large facility-based machines. ActiPatch Therapy is designed to meet the market demand for an effective, inexpensive, drug-free, therapeutic agent for the soft tissue injury market.

Through September 30, 2006, the Company has a cumulative operating loss of approximately $5,295,000 and negative working capital of approximately $1,152,000.

ActiPatch Therapy reduces the swelling (edema) and inflammation that occurs after tissue injury which accelerates the healing process of such injury. As a result of the decreased inflammation, a decrease in the pain associated with the soft tissue injury often occurs. The US Food and Drug Administration ("FDA") and Health Canada (Canada's FDA) have approved ActiPatch Therapy for the treatement of edema following blepharoplasty, a procedure to remove fat from eyelids. Heath Canada's market clearance also included a specific clearance for the relief of pain associated with muscosketal disorders.

The Company believes that additional market opportunities exist for ActiPatch Therapy, including:

Sprains/Sports Injuries;

Wound Care;

Post-Surgical;

Fracture Management; and

Repetitive Stress Injuries

**The following are the regulatory milestones the Company has achieved:**

FDA market clearance for the treatment of edema following blepharoplasty.

ISO and CE Certifications (European and Common Union)

Health Canada Market clearance for the relief of musculoskeletal pain

The clinical effectiveness of the product has been well established. Testing performed at the Bioelectromagnetics Research Laboratory at the State University of New York has shown that ActiPatch Therapy provides an adequate dosage of electromagnetic energy for the treatment of soft tissue, and that its power at the skin level is equivalent to that of traditional high-power devices. The power level is six to nine orders of magnitude higher than that which is required to show a biological effect. It also demonstrated that the cumulative effect of continuous delivery provides greater therapeutic benefit than sporadic treatments.

**Clinical Trials**

In 2006, the Company and the Lahey Clinic jointly announced a three-year program to study the effects of ActiPatch Therapy on a variety of soft tissue injuries and related medical conditions. The internationally renowned Lahey Clinic of Boston, whose faculty is affiliated with the Medical Schools of Harvard and Tufts, has committed to initiating a number of double-blind clinical studies on ActiPatch Therapy in the areas of plastic surgery, orthopedics and chronic wound care. Results from these clinical trials will be submitted to the United States Food and Drug Administration (the "FDA") for expanded indications for the use of ActiPatch Therapy.

**Significant Strategic Marketing Relationships Recently Established**

The Company, on December 4, 2003 signed an exclusive three-year supply and distribution agreement with Byron Medical, Inc. ("Byron") a subsidiary of Mentor Corporation (NYSE:MNT), a large supplier of medical products worldwide, to cover marketing of ActiPatch Therapy products to plastic surgeons worldwide. For the six months ended September 30, 2006 sales to Byron were approximately $97,000. The Byron Medical agreement is dated December 4, 2003. Byron is a wholly owned subsidiary of Mentor Corp., Santa Barbara, California. Mentor has announced that it intends to shut down its Byron Medical operations. The Company is negotiating with a major medical supplies distributor to market and sell its products to plastic and other surgeons. Should the Company not secure new distributors sales could be significantly impacted.

In July 2005, the Company announced an agreement with MaxMed Technologies ("MaxMed"), maker of the PedAlign ("PedAlign") brand of custom orthotics products. The new wearable and disposable ActiPatch Therapy will be available as an insert into the PedAlign product as a unique offering to providers that order PedAlign custom orthotic products. At the present time the Company is not doing a significant amount of business with MaxMed.

In November 2005, the Company announced a partnership with Profoot, Inc. ("Profoot") for distribution of the ActiPatch Therapy product in Canada. The product will be available at prominent retail stores throughout Canada. Profoot is America's second largest brand of consumer foot care products and the brand is available at tens of thousands of mass-retail outlets in Canada, the U.S. and 20 other countries. The Company has also entered into a distribution agreement with Virginia-based Medical Sales Professionals, Inc (MSP). MSP sells and distributes medical supplies to professional and college sports teams and health care providers. Currently, ActiPatch Therapy is used by 14 professional sports teams. The Company does not expect significant sales volume from the professional or college market segment. In September 2006 the Company signed a Sales Agent Agreement with Extremity Solutions & Seacoast Surgical, of Attleboro, Massachusetts. Extremity Solutions & Seacoast Surgical will sell the ActiPatch product in six New England states and in October 2006 announced that Henry Schein, Inc., the largest provider of healthcare products and services to office-based practitioners in the North American and European markets has agreed to sell and distribute ActiPatch(TM). The amount of sales from these two companies has not been determined. Additionally, the Company is in the early stages of negotiations with other companies to distribute our products. However, there is no assurance that distribution agreements will be finalized.

**Risk Factors**

As with most therapeutic agent products, the development of our products is subject to numerous risks, including the inability to obtain necessary regulatory approvals to market the products, our ability to satisfy future capital requirements and implement expansion plans, failure of physicians and patients to accept and use our products, competition from established entities, protection of proprietary information and dependence on third party collaborators to conduct research and development of the products. For a more detailed discussion of some of the risks associated with our Company, you are urged to carefully review and consider the section entitled "Risk Factors" beginning on page 7 of this prospectus.

**General**

The Company's principal executive offices are located at 4539 Metropolitan Court, Frederick, Maryland 21704, and the Company's telephone number at that address is (301) 644-3906. The Company has a corporate internet website at http://www.bioelectronicscorp.com. The reference to this website address does not constitute incorporation by reference of the information contained therein.

**About This Offering**

This prospectus relates to the resale of up to 23,182,889 shares of Common Stock, of which 10,451,389[(1)] shares are issuable upon the conversion of promissory notes, 3,420,000 shares issued in connection with the Company's April 4, 2005 Private Placement Offering and 9,311,500 shares issuable upon the exercise of outstanding warrants of our Company by certain selling stockholders identified in this prospectus. All of the 23,182,889 shares, when sold, will be sold by these selling stockholders. The selling stockholders may sell their Common Stock from time to time at prevailing market prices. We will not receive any proceeds from the sale of the shares of Common Stock by the selling stockholders.

Common Stock Offered

23,182,889 shares

Common Stock Offered by the Selling Stockholders

23,182,889 shares, including 9,311,500 shares issuable by the Company if the selling stockholders elect to exercise their warrants[(2)]

Common Stock Outstanding at September 30, 2006(3)

68,357,019 shares

Use of Proceeds of the Offering

The Company will not receive any of the proceeds from the sale of the shares, it may receive the proceeds from the exercise, if any, of the warrants included therein.

Pink Sheet Ticker Symbol

BIEL

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(1) The 10,451,389 shares that are issuable, at $0.18 per share, upon the conversion of the $1,000,000 convertible notes equal to 5,555,556 and 416,667 shares that are being issued in lieu of the payment of accrued interest and liquidated damages of $75, 000, a total of 5,972,222 shares , multiplied by 175%"

(2) The 9,311,500 warrants relate to the April 4, 2005 sale of stock, 3,420,000 warrants plus a commission to the broker for this transaction of 491,500 warrants and the December 8, 2005 convertible debt, 5,000,000 warrants plus the commission to the broker for this transaction, 400,000 warrants

(3) Does not include (i) 10,451,389 shares that are issuable upon the conversion of outstanding convertible notes at $0.18 per share, (ii) 167,000 restricted compensatory shares which have been earned and not issued to a former corporate officer (iii) 9,311,500 shares issuable upon the exercise of outstanding warrants at exercise prices ranging from $.33 to $.50 per share, subject to adjustment, or (iv) 2,765,000 shares issuable upon the exercise of outstanding options at exercise prices ranging from $.30 to $.50 per share, subject to adjustment, granted under the BioElectronics Equity Incentive Plan (the "Plan").

**Selected Financial Information**

The selected financial information presented below is derived from and should be read in conjunction with our consolidated financial statements, including notes thereto, appearing elsewhere in this prospectus. See "Financial Statements."

**Summary Operating Information**

| | Year Ended December 31, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2005** | **2004** | **2006** | **2005** |
| | (Restated) | | (Unaudited) | (Restated) |
| Net revenues | $ 303,690 | $302,002 | $ 306,776 | $ 251,611 |
| Loss from operations | $1,844,210 | $771,127 | $1,622,649 | $1,034,675 |
| Net loss | $1,914,053 | $792,799 | $1,986,186 | $1,068,515 |
| Net loss per common share | $ 0.033 | .$ 0.017 | $ 0.031 | $ 0.019 |
| Weighted average number of common shares Outstanding | | | | |
| Basic and Diluted | 57,626,059 | 45,976,334 | 64,970,101 | 56,014,225 |

**Summary Balance Sheet Information**

| | **September 30, 2006** |
|---|---|
| Working capital | $ (1,152,000) |
| Total assets | $ 885,275 |
| Total liabilities | $ 2,431,199 |
| Stockholders' deficiency | $ 1,545,924 |

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## RISK FACTORS

*You should carefully consider the risks described below before investing in the Company. We consider these risks to be significant to your decision whether to invest in our Common Stock at this time. If any of the following risks actually occur, our business, results of operations and financial condition could be seriously harmed, the trading price of our Common Stock could decline and you may lose all or part of your investment.*

**Risks Relating to Our Business**

***The Company has a limited operating history, and there is no assurance that the Company will ever be profitable.*** The Company is a development stage company, and the Company faces risks and difficulties frequently encountered in connection with the operation and development of a new and expanding business. The Company has a limited operating history on which an evaluation of the Company and its business can be based. The likelihood of the Company's future success must be considered in light of such limited operating history, as well as the problems, expenses, difficulties, complications and delays frequently encountered in connection with a new business. There can be no assurance that the Company's future revenues will ever be significant or that the Company's operations will ever be profitable.

***The Company has a history of operating losses and the Company anticipates that it will incur future operating losses.*** The Company was incorporated on April 1, 2000. Through September 30, 2006 the Company recorded a cumulative operating loss of approximately $5,295,000. The Company expects to incur additional losses until sufficient sales of its ActiPatch Therapy products are achieved. The Company has not yet commenced shipping of any products in substantial volumes. The Company's limited operating history makes the prediction of future operating results difficult or impossible to make. There can be no assurance that the Company's future revenues will ever be significant or that the Company's operations will ever be profitable.

***The Company's ability to operate is conditioned on the Company's ability to obtain additional financing.*** The Company's ability to satisfy its future capital requirements and implement its expansion plans will depend upon many factors, including the financial resources available to it, the expansion of the Company's sales and marketing efforts and the status of competition, if any. The Company believes that current and future available capital resources, including the net proceeds from sale of the Company's products, will be sufficient to fund its operations at current levels for twelve (12) months. However, the exact amount of funds that the Company will require will depend upon many factors, and it is possible that the Company will require additional financing prior to such time. There can be no assurance that additional financing will be available to the Company on acceptable terms, or at all. If additional funds are raised by issuing equity securities, further dilution to the existing stockholders will result. If adequate funds are not available, the Company may be required to delay, reduce or eliminate its programs or obtain funds through arrangements with partners or others that may require the Company to relinquish rights to certain of its products, technologies or other assets. Accordingly, the inability to obtain such financing could have a material adverse effect on the Company's business, financial condition and results of operations.

***The Company depends on a limited number of products and almost all of the Company's sales have been derived from sales of the Company's existing ActiPatch Therapy dermal patches.*** Although additional products are currently being developed, there can be no assurance that these development efforts will be successful or, if successful, that resulting products will receive market acceptance, generate significant sales or result in gross profits. The Company believes that success in the general surgical market is somewhat dependent on product acceptance by plastic surgeons. The Company's future operating results, particularly in the near term, are significantly dependent upon market acceptance of its ActiPatch Therapy product line. Because virtually all of the Company's sales are derived from its ActiPatch Therapy product line, failure to achieve broader market acceptance of pulsed electromagnetic energy therapy as a result of competition, technological change or other factors, or the failure to successfully market any new or enhanced versions of existing products or other factors, would have a material adverse effect on the business, operating results and financial condition of the Company.

***The acceptance of the Company's products depends upon results of clinical studies for new applications.*** Clinical studies of new applications of the Company's ActiPatch Therapy products are in various stages of completion, and further clinical studies of the Company's products are expected to be conducted in the future. Clinical studies of the Company's products that result in unfavorable or inconclusive findings, or significant delays in completing clinical studies, could have a material adverse effect on the Company's business, financial condition and results of operations. There can be no assurance that the findings derived from ongoing clinical studies will be favorable or conclusive with regard to the Company's products or that the medical community will react positively to such findings as clinical studies are completed.

***The Company faces a risk of technological obsolescence.*** The medical device market is characterized by rapid, technological innovation and change. Many companies are engaged in research and development of devices, drugs and alternative methods to reduce swelling, relieve pain and enhance the healing of surgical incisions, accidental wounds, sprains, strains and chronic wounds. The Company's products could be rendered obsolete as a result of future innovations.

***The Company faces extensive competition from the medical device market, and potential competitors, with a longer operating history and greater resources, may harm the Company's business.*** The medical device market is very competitive and competition is likely to increase. Increased competition may result in price cuts, reduced gross margins and loss of market share, any of which could seriously harm the Company's business. Many of the Company's competitors have, and potential competitors may possess, longer operating histories and significantly greater financial, technical, personnel and other resources than the Company. Competitors and potential competitors may also have larger, more established research and development departments and greater name and brand recognition than the Company possesses. These greater resources may permit them to implement extensive advertising, sales, promotions and programs that the Company may not be able to match. Better financed competitors may also have greater success in future research and development efforts. As these competitors enter the field, the Company's sales growth may fail to increase, despite its efforts to continue to design superior products. There can be no assurance that the Company will have the ability to compete successfully in this environment. If the Company is unable to compete successfully, the Company's business will be seriously harmed.

***The Company must manage its expansion to maintain its level of service to its customers.*** The Company may encounter significant strain and additional demands on its infrastructure and resources as it expands its business. The Company's ability to compete effectively and to manage future expansion will require it to continue to add to its infrastructure and management controls and to expand, train and manage its workforce. If the Company is unable to manage its expansion, the Company's level of service will decline, it may lose customers and its revenues and growth will be limited.

***The Company has a high level of dependence on key existing and future personnel for its success.*** The Company's success will depend, to a large degree, upon the efforts and abilities of its officers and key management employees, including, without limitation, Andrew J. Whelan, the President and Chairman of the Board of Directors (the "Board") of the Company. The loss of the services of one or more of the Company's key employees could have a material adverse effect on its operations. The Company has employment agreements with certain of its employees, but does not maintain a key man life insurance policy on any employee. In addition, as its business plan is implemented, the Company will need to recruit and retain additional management and key employees in virtually all phases of its operations. Key employees will require not only a strong background in the medical device industry, but a familiarity with the markets in which the Company competes. The Company may not be able to successfully attract and retain key personnel.

***The Company relies on third parties for the supply and manufacturing of its products, and inability of the Company to retain such third party manufacturers may significantly harm the Company's business .*** BioElectronics subcontracts the manufacturing of its products to third parties. These parties manufacture the products to BioElectronic's specifications. The Company does not currently have manufacturing facilities or personnel to independently manufacture its products. If for any reason the Company is unable to obtain or retain third party manufacturers on commercially acceptable terms, it may not be able to distribute its products as planned. If the Company encounters delays or difficulties with contract manufacturers in producing or packaging its products, the distribution, marketing and subsequent sales of these products will be adversely affected. The Company may have to seek alternative sources of supply or abandon or sell product lines on unsatisfactory terms. The Company may not be able to enter into alternative supply arrangements on commercially acceptable terms, if at all. There can be no assurance that the manufacturers the Company has engaged will be able to provide sufficient quantities of these products or that the products supplied will meet the Company's specifications. In addition, production of the Company's products may require raw materials for which the sources and quantities are limited. An inability to obtain adequate supplies of raw materials could significantly delay development, regulatory approval and marketing of the Company's products.

***The Company is dependent on third party distributors to distribute its products. Loss of any of these distributors may affect the Company's ability to provide customers with its products.*** The Company currently utilizes several third party medical device distributors to distribute its products. If for any reason the Company is unable to obtain or retain third party distributors on commercially acceptable terms, it may not be able to distribute its products as planned. If the Company encounters delays or difficulties with contract distributors, the distribution, marketing and subsequent sales of these products will be adversely affected, and the Company may have to seek alternative sources of distribution or abandon or sell product lines on unsatisfactory terms. The Company may not be able to enter into alternative distribution arrangements on commercially acceptable terms, if at all. There can be no assurance that the distributors the Company has engaged will be able to provide sufficient distribution of the Company's products in order for the Company to meet its current or future obligations to its customers.

***The Company faces the risk of product liability claims.*** The Company faces an inherent business risk of exposure to product liability claims in the event that the use of its products are alleged to have resulted in adverse side effects, such as injury, illness or death. The Company also may be required to recall some of its products if they are damaged or mislabeled. Such events could result in product liability claims or adverse publicity. While the Company currently maintains product liability insurance, a significant product liability judgment against the Company or a widespread product recall, to the extent either such event is in excess of the limits of its product liability insurance, could substantially impair the Company's business, financial condition and results of operations.

***The Company may not be able to adequately protect its intellectual property.*** The Company believes that its success depends to a significant degree upon its ability to develop proprietary technology and its ability to protect the proprietary aspects of its products. The Company acquired 44 patents that have now expired. Instead of filing for FDA regulatory delay patent extensions, the Company opted to file new patent applications to cover its technological improvements, affixing and delivery methods and medical treatments. The Company has approximately 150 new patent claims pending. We have filed patent applications in the United Sates, the European Common Market, Canada, and the other major markets such as Japan, South Korea, Mexico and Australia.

The Company will continue to seek patent protection for its products. There can be no assurance that any patent that has been or may be issued will cover products the Company intends to sell, or if it does, will not subsequently be invalidated for any of a variety of reasons.

The Company relies upon a combination of laws and contractual restrictions, including restrictions contained in confidentiality agreements, to establish and protect its rights to any intellectual property that it creates. Any infringement of the Company's proprietary rights could result in significant litigation costs, and any failure to adequately protect its proprietary rights could result in the Company's competitors offering similar products, potentially resulting in loss of a competitive advantage and decreased revenues. Despite the Company's efforts to protect its proprietary rights, existing patent laws afford only limited protection. In addition, the laws of some foreign countries do not protect the Company's proprietary rights to the same extent as do the laws of the United States. Attempts may be made to copy or reverse engineer aspects of the Company's products or to obtain and use information that the Company regards as proprietary. Accordingly, the Company may not be able to prevent misappropriation of its technology or deter others from developing similar technology. Furthermore, policing the unauthorized use of the Company's products is difficult. Litigation may be necessary in the future to enforce the Company's intellectual property rights or to determine the validity and scope of the proprietary rights of others. This litigation could result in substantial costs and diversion of resources and could significantly harm the Company's business.

***The Company may face infringement of third-party rights claims in the future.*** In recent years, there has been significant litigation in the United States and elsewhere involving patents and other intellectual property rights. Third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in the Company's business. Any infringement claims, with or without merit, could be time consuming, result in costly litigation, and divert the efforts of the Company's technical and management personnel. If the Company is unsuccessful in defending itself against these types of claims, it may be required to do one or more of the following:

stop selling those products that use or incorporate the challenged intellectual property;

attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or

redesign those products that use the relevant technology, which the Company may not be able to do on a timely or cost effective basis, or at all.

In the event a claim against the Company is successful and the Company can not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign its products to avoid infringement, the Company's business will be significantly harmed, which would have a material adverse effect on the Company's financial condition and results of operations.

***The Company may face royalty claims, which may result in litigation and divert the efforts of the Company's personnel.*** In April 2000, the Company acquired from Patricia A. Whelan, the wife of Andrew J. Whelan, the Chairman of the Board and President of the Company, certain

patents (including all 44 patents currently owned by the Company), technology, research, trademarks and other assets relating to pulsed electromagnetic energy therapy (the "Acquired Assets"). The Acquired Assets were acquired by Mrs. Whelan in October 1994 from Shannon Investments, Inc. ("Shannon") in a transaction in which Mrs. Whelan agreed to pay to Shannon (i) 20% of any consideration received by Mrs. Whelan, directly or indirectly, from the Acquired Assets, including any sales of products utilizing any of the Acquired Assets and (ii) a 2% royalty payment on any sales by Mrs. Whelan of products utilizing the Acquired Assets. In such transaction, Shannon acknowledged that Mrs. Whelan had the authority to dispose of or retain the Acquired Assets in her sole discretion. Prior owners of the Acquired Assets transferred the Acquired Assets under transfer and assignment agreements that included similar 2% royalty payments. While the Company believes it is not responsible for the payment of any royalty or other payments to any prior owner(s) of the Acquired Assets, there can be no assurance that any of such prior owners will not claim that royalty or other payments are due and owing by the Company. Any such claims, with or without merit, could be time consuming, result in costly litigation, and divert the efforts of the Company's management personnel.

***The profitability of our Company may be affected by efforts to reduce costs associated with health care.*** The levels of revenues and profitability of pharmaceutical and medical device companies may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of health care through various means. In the United States there have been, and the Company expects that there will continue to be, a number of federal and state proposals to control health care costs. There have been a number of proposals introduced to Congress to comprehensively reform the nation's health care system. Some of the proposed legislation has contained measures intended to control public and private spending on health care as well as to provide universal public access to the health care system. In addition, some of the proposed legislation included limitations on Medicare and Medicaid reimbursement for medical products and services and called for the creation of a committee to monitor and evaluate the pricing of new medical products and services. Although no such legislation has been passed by Congress, federal, state and local officials and legislators (and certain foreign government officials and legislators) have proposed or are reportedly considering proposing a variety of additional reforms to the health care systems in their respective jurisdictions, including reforms that may affect the pharmaceutical and medical device industries. It is uncertain what new legislative proposals, if any, might be adopted or what actions federal, state or third-party payers may take in response to any health care reform proposals or legislation. The Company cannot predict the effect health care reforms may have on its business or the business of its collaborators.

In the United States and elsewhere, sales of therapeutic products are dependent in part on the availability of reimbursement from third-party payers, such as government and private insurance plans. These third-party payers are increasingly challenging the prices charged for medical products and services. If the Company succeeds in bringing one or more products to the market, there can be no assurance that these products will be considered cost effective and that reimbursement to the consumer will be available or will be sufficient to allow the Company to sell its products on a profitable basis.

There can be no assurance that any product developed by the Company will gain market acceptance among health care providers. Even if the Company's proposed products gain market acceptance, sales of such products may be dependent on the availability of reimbursement from third-party health care payers, such as government and private insurance plans. If adequate coverage and reimbursement levels are not authorized by government and third-party payers for use of the Company's products, market acceptance will be adversely affected.

***Physicians and patients may not accept our device in comparison to competing products.*** Physicians and patients may not accept and use our device. Acceptance and use of the device will depend upon a number of factors, including perceptions by members of the health care community, including physicians, about the safety and effectiveness of the device; cost-effectiveness of the device relative to competing products; availability of reimbursement for the products from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. Because we expect sales of the current product device to generate substantially all of our product revenues for the foreseeable future, the failure of the device to find market acceptance would harm our business and could require us to seek additional financing.

***The Company may incur extensive costs to comply with regulatory requirements.*** The Company is subject to a variety of regulatory agency requirements in the United States and foreign countries relating to the products that the Company develops. The process of obtaining and maintaining required regulatory approvals and otherwise remaining in regulatory compliance can be lengthy, expensive and uncertain. The FDA inspects manufacturers of certain types of devices before providing a clearance to manufacture and sell such devices, and the failure to pass such an inspection could result in delay in moving ahead with a product or project. The Company is required to comply with the FDA's quality system regulation for the manufacture of medical products. In addition, in order for the devices that the Company designs to be exported, and for the Company and its customers to be qualified to use the "CE" mark in the European Union, the Company maintains EN International Standards Organization ("ISO") 13485:2003 certification. This certification, like the quality system regulation, subjects the Company's operations to periodic surveillance audits. To ensure compliance with various regulatory and quality requirements, the Company expends significant time, resources and effort in the areas of training, production and quality assurance. If the Company fails to comply with regulatory or quality regulations or other FDA or applicable legal requirements, the governing agencies can issue warning letters, impose government sanctions and levy serious penalties. In addition, the continued sale of the Company's products may be halted or otherwise restricted. Any such actions could have an adverse effect on the willingness of customers and prospective customers to do business with the Company. In addition, any such noncompliance or increased cost of compliance could have a material adverse effect on the Company's business, results of operations and financial condition.

***The Company is dependent on its ability to generate product revenues, and there is no guarantee that the Company will be able to produce such revenues.*** Our ability to generate product revenues will be diminished if the devices sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement. Our ability to commercialize the devices, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from government and health administration authorities; private health maintenance organizations and health insurers; and other healthcare payors. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, routinely challenge the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for patches. Even if the new product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate to cover such patches. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of the products, the post-approval market acceptance of our products could be diminished.

**Risks Relating to Our Common Stock**

***Disappointing quarterly revenue or operating results could cause the price of our Common Stock to fall.*** Our quarterly revenue and operating results are difficult to predict and may fluctuate significantly from quarter to quarter. If our quarterly revenue or operating results fall below the expectations of investors or security analysts, the price of our Common Stock could fall substantially. Our quarterly revenue and operating results may fluctuate as a result of a variety of factors, many of which are outside our control, including:

the amount and timing of expenditures relating to the rollout of our ActiPatch Therapy products;

our ability to obtain, and the timing of, additional regulatory approvals;

the rate at which we are able to attract customers within our target markets and our ability to retain these customers at sufficient aggregate revenue levels;

the availability of financing to continue our expansion;

technical difficulties in developing the products or network downtime; and

the introduction of new services, products or technologies by our competitors and resulting pressures on the pricing of our service.

***We do not intend to pay dividends on our Common Stock in the foreseeable future, which could cause the market price of our Common Stock and the value of your investment to decline.***

We expect to retain earnings, if any, to finance the expansion and development of our business. Our Board will decide whether to make future cash dividend payments. Such decision will depend on, among other things, the following factors:

our earnings;

our capital requirements;

our operating results and overall financial condition; and

our compliance with various financing covenants to which we are or may become a party.

***The market for our Common Stock is thinly traded, which could result in fluctuations in the valu***