BioElectronics Corp
Form 10-K
March 31, 2010

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2009

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to .

Commission File Number 021-74972

BIOELECTRONICS CORPORATION
(Exact name of registrant as specified in its charter)

Maryland	52-2278149
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification number)

4539 Metropolitan Court
Frederick, Maryland 21704
(Address of principal executive offices and zip code)

Phone: 301.874.4890
Fax: 301.874.6935
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:
None.

Securities registered under Section 12(g) of the Exchange Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes x No ¨

Indicate by check mark whether the issuer (1) has 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. (1) Yes x No ¨ (2) Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.45 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the ordinary shares, $0.001 par value per share ("Shares"), of the registrant held by non-affiliates on June 30, 2009 was $26,961,010.

The Company is authorized to issue 1,500,000,000 Shares. As of March 30, 2010, the Company has issued and outstanding 1,461,998,871 Shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

BIOELECTRONICS CORPORATION

FORM 10-K

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The statements contained in this Report that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results of operations and business, which can be identified by the use of forward-looking terminology, such as “estimates,” “projects,” “plans,” “believes,” “expects,” “anticipates,” “intends,” or the negative thereof or other variations thereon, or by discussions of strategy that involve risks and uncertainties. Management wishes to caution the reader of the forward-looking statements that such statements, which are contained in this Report, reflect our current beliefs with respect to future events and involve known and unknown risks, uncertainties and other factors, including, but not limited to, economic, competitive, regulatory, technological, key employee, and general business factors affecting our operations, markets, growth, services, products, licenses and other factors discussed in our other filings with the Securities and Exchange Commission, and that these statements are only estimates or predictions. No assurances can be given regarding the achievement of future results, as actual results may differ materially as a result of risks facing us, and actual events may differ from the assumptions underlying the statements that have been made regarding anticipated events. Factors that may cause our actual results, performance or achievements, or industry results, to differ materially from those contemplated by such forward-looking statements include, without limitation:

- The availability of additional funds to successfully pursue our business plan;
- The cooperation of industry service partners that have signed agreements with us;
- Our ability to market our services to current and new customers and generate customer demand for our products and services in the geographical areas in which we operate;
- The highly competitive nature of our industry;
- Our ability to retain key personnel;
- Our ability to maintain adequate customer care and manage our churn rate;
- Our ability to maintain, attract and integrate internal management, technical information and management information systems;
- Our ability to manage rapid growth while maintaining adequate controls and procedures;
- The availability and maintenance of suitable vendor relationships, in a timely manner, at reasonable cost;
- General economic conditions.

These forward-looking statements are subject to numerous assumptions, risks and uncertainties that may cause our actual results to be materially different from any future results expressed or implied by us in those statements.

These risk factors should be considered in connection with any subsequent written or oral forward-looking statements that we or persons acting on our behalf may issue. All written and oral forward looking statements made in connection with this Report that are attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Given these uncertainties, we caution investors not to unduly rely on our forward-looking statements. We do not undertake any obligation to review or confirm analysts’ expectations or estimates or to release publicly any revisions to any forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. Further, the information about our intentions contained in this document is a statement of our intention as of the date of this document and is based upon, among other things, the existing regulatory environment, industry conditions, market conditions and prices, the economy in general and our assumptions as of such date. We may change our intentions, at any time and without notice, based upon any changes in such factors, in our assumptions or otherwise.

PART I

Item 1. Business.

1. Form and year of organization: BioElectronics Corporation ("the Company") was formed as a Maryland Corporation in April 2000.

2. Description of the Company's business as a smaller reporting company.

a. Principal products or services and their markets: BioElectronics Corporation is the maker of inexpensive, drug–free, anti-inflammatory medical devices and patches; its primary SIC code is 3845. The Company's wafer thin patches contain an embedded microchip and battery that deliver pulsed electromagnetic energy, a clinically proven and widely accepted anti-inflammatory and pain relief therapy that heretofore has only been possible to obtain from large, facility-based equipment. BioElectronics markets and sells its current products under the brand names ActiPatch®, Allay™, RecoveryRx™ and HealFast™.

The dermal patch delivery system creates a multitude of new product opportunities for chronic and acute inflammatory conditions. The market potential is estimated at $10 billion or 400 million incidents worldwide, according to a study titled "Report on BioElectronics, Corp. – Sizing the Market Opportunity and Assessing Possible Outcomes for the Company." The current market for medical devices is United States, Europe, and Asia. The distinctive value proposition of the device is the delivery of drug-free therapy that reduces pain and inflammation and accelerates healing by 30% to 50% when compared with the present standard methods of patient care. The current major applications are:

- Medical Surgeries
- Chronic Wounds
- Oral Surgeries
- Sprains and Strains
- Lower Back Pain
- Chronic Repetitive Stress Injuries, Heel Pain, Carpal Tunnel, Bursitis, etc.

The Company manufactures a medical device that reduces inflammation without the use of drugs, topical ointments, heat or cold therapy. Inflammation occurs following a variety of insults such as surgery, lacerations of the skin and soft tissues, sprains and strains, (including those of the low back), repetitive stress injuries such as plantar fasciitis, carpal tunnel syndrome, and tennis elbow. The Company has branded its device for many applications and separated the market for the products into four distinct segments- retail products designed for consumer use, a women's health product, medical professional products and veterinary use products.

How the device works:

The body's natural response to soft tissue trauma is a localized inflammatory reaction. The damaged cells separate to prevent the transmission of infection. The cells leak fluid and cellular components break down while the cellular debris causes inflammation, swelling and pain.

This inflammatory response, which has a physiologic protective action, in fact creates an environment in which the healing process is actually prolonged or stalled in chronic wounds.

The devices use proven medical technology to truncate the body's inflammatory response (i.e. breaks the cycle of chronic inflammation). It does this by delivering pulsed electromagnetic energy directly to the affected area and driving out the edematous fluid along with byproducts of the damaged tissue. This provides a well-demonstrated and significant overall improvement in the restorative and recovery process following injury. As a result the pain associated with soft tissue injury is often substantially reduced.

The Retail Products and Market

The Company has developed distinct retail treatment kits.

Five kits are marketed as ActiPatch® Therapy for Pain - for Back, Knee, Wrist, Tennis Elbow, and Heel Pain. The kits are unique to the market as drug free, anti-inflammatory therapeutic agents that rapidly and safely reduce pain, swelling and healing times.

Each retail kit is designed for either 360 or 720 hours of use and includes a free extremity wrap and an unconditional money back guarantee. Priced at $39.95, the cost benefit of these kits is an overwhelming sales proposition. These products are currently available in the retail environment in Canada and Europe.

Women's Health Product and Market

The Allay™ Menstrual Pain Therapy kit addresses dysmenorrhea, the painful monthly cramps experienced by 40% of women during sometime in their life. The market for drug-free relief is enormous. Current treatment such as heat pads and medications such as NSAIDs are not as effective, nor as safe.

Medical Professionals Market

The Company has been marketing to the U.S. medical market for almost three years. Most of the past sales efforts have centered on plastic surgery and podiatry. Sales increases have been very slow, partly due to the lack of clinical evidence, partly due to the lack of a skilled sales force and partly due to less than desirable product design. In 2008, the Company redesigned the product line, refocused on the plastic surgery, Orthopedic and Sports Medicine markets and branded this line under the trademark name RecoveryRx™. This current product line consists of five distinct kits:

- Jaw Surgery Recovery Kit
- General Surgery Recovery Kit
- Breast Recovery Kit
- C-Section Recovery Kit
- Eye Surgery Recovery Kit

Also in development are products for hernias and other surgeries including Dental and Oral surgery. Additionally, the medical products are being used and tested for eye disease, noses surgeries, skin grafts, and wound care. Finally, the Company recently obtained reimbursement approval from the Maryland state Medicaid program for kidney compromised patients, and we believe that we can also obtain reimbursement for cardiovascular and diabetic patients.

The Veterinary Market

The Company has a distribution agreement with eMarkets Group of North Caldwell, New Jersey. The products are marketed under the trade names HealFast and the HealFast PetPatch. The products are a drug-free therapy for horses, cats and dogs that reduce swelling and pain, while speeding healing of muscle and tendon injuries, sores and incisions. There are currently approximately 162 million companion animals in the United States and about 7 million horses.

b. Distribution methods of the products or services: Most of the sales are through distribution agreements with companies which sell items on a wholesale basis to retail outlets, such as drug stores and medical supply outlets.

c. Status of any publicly announced new product or service: During 2009, our focus was on developing product, obtaining additional domestic and international distribution channels, conducting market research, completing additional clinical trials, eliminating debt, and strengthening the balance sheet. The motivations for continued clinical trials are marketing enrichment and obtaining additional U.S. Food and Drug Administration (FDA) approved therapeutic indications for existing and future products. Securing additional U.S. FDA approval is central to market entry and product acceptance. Below are listed currently planned or underway clinical studies:

Plantar Fasciitis (Heel Pain) Study – Chief Investigator, Joel Brook, D.P.M. – A double-blind randomized study spanning a 7-day treatment period. Subjects recorded pain levels using a Visual Analogue Scale (VAS). Subjects also kept a log of medication taken during the 7-day treatment period. Clinical data demonstrated a reduction in pain in the active ActiPatch group and a large clinically significant different in pain medication usage. The active ActiPatch group took 55% less medication taken than the placebo ActiPatch group.

Delayed Onset Muscle Soreness Study – Chief Investigator, Sheena Kong, M.D. - This was an observational study to evaluate the treatment of Delayed Onset Muscle Soreness (DOMS). After a vigorous resistance training exercise regiment designed to induce DOMS, 102 study participants were placed into one of three groups: 1) a control group; 2) a group that utilized the ActiPatch device; and 3) a group that received over-the-counter strength acetaminophen in the form of Extra Strength Tylenol after a vigorous resistance training exercise regiment designed to induce DOMS. The data yielded by this study appears to demonstrate that the use of ActiPatch for the treatment of Delayed Onset Muscle Soreness (DOMS) is both safe and effective. Additionally, the data yielded by the study appears to demonstrate that the continuous use of ActiPatch will result in significantly less DOMS-related pain and muscle soreness compared to a treatment regiment consisting of an OTC dosage of acetaminophen.

Primary Dysmenorrhea (Menstrual Pain) Study – Primary Investigator, Barry Eppley, M.D.D.M.D. – This clinical study was a placebo controlled, double-blind, prospective randomized trial comparing the efficacy and effectiveness of an active Allay device to an inactive (placebo) Allay device. The primary outcome measure was reduction of menstrual pain in comparison with prior baseline scores. The intensity of pain was measured using a VAS. Of the active group, 77.1% reported either complete elimination or reduction in their typical menstrual pain symptoms. Allay was demonstrated to be a safe and effective drug-free method for the treatment of primary dysmenorrhea. It may be used as a primary treatment method for those women with moderate dysmenorrhea who prefer not to take oral medication. In more severe cases of dysmenorrhea, it could be an adjuvant treatment to reduce the amount of oral medications needed. Further controlled clinical studies are needed for further evaluation.

d. Competitive business conditions and the smaller reporting company's competitive position in the industry and methods of competition: The manufacture, distribution and sale of medical devices and equipment designed to relieve swelling and pain or to treat chronic wounds is competitive and some of the Company's competitors possess significant product sales, and greater experience, financial resources, operating history and marketing capabilities than us. For example, Diapulse Corporation of America, Inc. manufactures and markets devices that are deemed by the U.S. FDA to be substantially equivalent to some of the Company's products. Regenesis Biomedical and Ivivi Technologies also manufacture and market devices that deliver PEMF therapy. A number of other manufacturers, both domestic and foreign, and distributors market shortwave diathermy devices that produce deep tissue heat and may be used for the treatment of certain of the medical conditions that the Company's products are used for. The Company's products may also compete with pain relief drugs and pain relief medical devices, as well as other forms of treatment.

The Company's ability to compete effectively with other companies is materially dependent upon the proprietary nature of its technologies. We rely primarily on patents and trade secrets to protect our technologies. There can be no assurance that the Company will not be required to resort to litigation to protect its patented technologies and other proprietary rights or that we will not be the subject of additional patent litigation to defend its existing and proposed products and processes against claims of patent infringement or any other intellectual property claims. Such litigation could result in substantial costs, diversion of management's attention, and diversion of Company resources.

The Company strives to protect its trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. If our employees or other parties breach our confidentiality agreements and non-competition agreements or if these agreements are not sufficient to protect our technology or are found to be unenforceable, our competitors could acquire and use information that we consider to be our trade secrets, and we may not be able to compete effectively. Some of the Company's competitors have substantially greater financial, marketing, technical and manufacturing resources, and we may not be profitable if our competitors are also able to take advantage of our trade secrets.

The Company may decide for business reasons to retain certain knowledge that it considers proprietary as confidential and elect to protect such information as a trade secret, as business confidential information or as know-how. In that event, the Company must rely upon trade secrets, know-how, confidentiality and non-disclosure agreements and continuing technological innovation to maintain our competitive position. There can be no assurance that others will not independently develop substantially equivalent proprietary information or otherwise gain access to or disclose such information.

The Company's ability to commercially exploit its products must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the development of new medical devices and products. We believe that in order to continue to be competitive, we need to develop and maintain sufficient market share. Our methods of competition include continuing our efforts to develop and sell products, which, when compared to existing products, perform more efficiently and are available at prices that are acceptable to the market; displaying our products and providing associated literature at major industry trade shows; and pursuing alliance opportunities for the distribution of our products. We further believe that our competitive advantages with respect to our products include: the clinical efficacy of our technology and products, the benefits of treatments utilizing our products, which include treatments that are non-invasive and painless, are free from known side-effects and are not susceptible to overdose or abuse, do not require special training to implement, may be applied to any part of the body; and the relevant experience of the members of our consultants including, among others, Dr. David Genecov, an internationally recognized surgeon, and Dr. Kenneth McLeoad, a principal innovator in PEMF technology.

e. Sources and availability of raw materials and the names of principal suppliers: The raw materials used as components in Company's products, mainly bandaging material and electronic circuit boards, are readily available worldwide. The Company's manufacturers work on behalf of many similar companies, and possess additional capacity to fulfill Company's anticipated needs.

f. Patents, trademarks, licenses, franchises, concessions, royalty agreements or labor contracts, including duration: The rights to the technology and patents supporting the development of the current product line were acquired by BioElectronics in 2000. Prior to that time, the previous owners of the technology and patents had invested over $4.65 million in electronic engineering prototypes, production runs, and in confirming clinical studies. The Company has been issued U.S. Patent #7551957B2 and has additional patents pending in the United States and worldwide.

g. Need for any government approval of principal products or services. If government approval is necessary and the smaller reporting company has not yet received that approval, discuss the status of the approval within the government approval process:

- The Company was granted its first approval from the U.S. FDA under a 510(k) in August 2002. Prior to U.S. FDA approval and the establishment of its research and development group, PAW, LLC (the family of Andrew Whelan, President) paid and expensed the cost of development.

- In December 2004, the Company received ISO and CE (European Common Market) certification. In 2005, Health Canada approved ActiPatch® Therapy for the relief of pain in musculoskeletal complaints.

- In early 2008, the Company redesigned its product and manufacturing process and established new disease specific products and distinct medical and retail product lines. It also shifted its attention to international sales.

Generally during its history, with regard to its efforts in 2009 and beyond, the Company cannot assure that it will be successful in obtaining U.S. FDA clearance, and without such clearance, we will be unable to enter the relief of pain and discomfort associated with primary dysmenorrhea market in the United States. There are numerous medications used in the treatment of pain and discomfort associated with primary dysmenorrhea, and if we receive clearance to market this product, we intend to offer it as an alternative to such medications. These commonplace medications have been required to carry warning labels due to potential dangerous side-effects (and some withdrawn altogether), as compared to our non-invasive, drug-free alternative device with no known side-effects.

h. Effect of existing or probable governmental regulations on the business: After a device is placed on the market, within the United States, numerous regulatory requirements apply. These include:

Ø Quality System Regulations, or QSR, which require finished device manufacturers, including contract manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

Ø labeling regulations and U.S. FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses;

Ø medical device reporting regulations, which require that manufacturers report to the U.S. FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of that or a similar company device were to recur; and

Ø post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The U.S. FDA has broad post-market and regulatory enforcement powers. The Company is subject to unannounced inspections by the U.S. FDA to determine the Company’s compliance with the QSR and other regulations, and these inspections include the manufacturing facilities of BioElectronics Corporation. Our location has been registered with the U.S. FDA as a Medical Device establishment. Such registration is renewable annually, and although we do not believe that the registration will fail to be renewed by the U.S. FDA, there can be no assurance of such renewal. The failure of the Company to obtain any annual renewal would have a material adverse effect on us.

Failure to comply with applicable regulatory requirements can result in enforcement action by the U.S. FDA or the Department of Justice, which may include any of the following sanctions, among others:

- Ø fines, injunctions and civil penalties;
- Ø mandatory recall or seizure of our products;
- Ø operating restrictions and partial suspension or total shutdown of production;
- Ø refusing our requests for 510(k) clearance or pre-market approval of new products or new intended uses;
- Ø withdrawing 510(k) clearance or pre-market approvals that are already granted; and
- Ø criminal prosecution.

The U.S. FDA also has the authority to require us to repair, replace or refund the cost of any medical device that has been manufactured for us or distributed by us. If any of these events were to occur, they could have a material adverse effect on our business. We also are subject to a wide range of federal, state and local laws and regulations, including those related to the environment, health and safety, land use and quality assurance. We believe that we are in complete compliance with these laws and regulations as currently in effect, and our compliance with such laws will not have a material adverse effect on our capital expenditures, earnings and competitive and financial position.

The primary regulatory environment in Europe is that of the European Union, which consists of 27 countries encompassing most of the major countries in Europe. Three member states of the European Free Trade Association have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet European Union requirements.

The European Union has adopted numerous directives and European Standardization Committees have promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear a CE conformity marking (which stands for Conformite Europeenne), indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, the member states of the European Free Trade Association and countries which have entered into a Mutual Recognition Agreement. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer of the product and a third-party assessment by a Notified Body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. An assessment by a Notified Body in one member state of the European Union, the European Free Trade Association or one country which has entered into a Mutual Recognition Agreement is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 certifications are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking.