BOVIE MEDICAL CORP
Form 10-K/A
September 18, 2009

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008
Commission file number 0-12183

BOVIE MEDICAL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware No.	11-2644611
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

734 Walt Whitman Rd., Melville, New York 11747
(Address of principal executive offices)

(631) 421-5452
(Issuer's telephone number)

Title of each Class	Name of each Exchange on which registered
Common Stock, $.001 Par Value	NYSE Alternext Market

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

Indicate by check mark if the Company is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes: o No x
Indicate by check mark if the Company is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes: o No x
Indicate by check mark whether the registrant (I) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See definition of "large accelerated filer", "accelerated filer" and "small reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Small reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
Yes ¨ No x
The aggregate market value of the voting stock held by non-affiliates computed by reference to the price at which the stock was sold, or the average bid and asked prices of such stock, as of March 2, 2009 was approximately $101,800,000

The number of shares of the registrant's $.001 par value common stock outstanding on the NYSE Alternext exchange as of March 2, 2009 was 16,987,698

Company Symbol-BVX Company SIC (Standard Industrial Code)-3841

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive Proxy Statement relating to the Annual Meeting of Shareholders which was held on November 6, 2008 are incorporated by reference into Part I.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends the original Annual Report on Form 10-K for the year ended December 31, 2008 of Bovie Medical Corporation (the "Company") that initially was filed with the Securities and Exchange Commission (the "SEC") on March 13, 2009 (the "Original 10-K"). This Amendment is being filed to amend Item 1A Risk factors of the Original 10-K to provide better clarification in line with section 503(c) of Regulation S-K. In addition we have corrected two errors located on the signature page, the first being a typographical error which listed the incorrect year in the signature paragraph, and second we have included the Company’s officers and directors signatures that were erroneously omitted from our original Annual Report. Lastly, we have included exhibits that previously were omitted erroneously and accordingly amended the Exhibit Index.

Additionally, pursuant to the rules of the SEC, Part IV of the Original 10-K has been amended to contain currently dated certifications of the Company's chief executive officer and chief financial officer. As required by Section 302 and 906 of the Sarbanes-Oxley Act of 2002, the certifications of our chief executive officer and chief financial officer are attached to this Amendment as Exhibits 31.1, 31.2, 32.1 and 32.2.

Except as described above, no other amendments have been made to the Original 10-K. All other Items of the Original 10-K are unaffected by this Amendment and therefore should be read in conjunction with this form 10-K/A. This Amendment does not reflect events occurring after March 13, 2009 or modify or update the disclosure contained in the Original 10-K in any way other than as required to reflect the revisions discussed above.

Bovie Medical Corporation
2008 Form 10-K/A Annual Report

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ITEM 1A. Risk factors

In addition to risks and uncertainties in the ordinary course of business, important risk factors that may affect us are discussed below.

Risks Relating to Our Business

Current challenges in the commercial and credit environment may adversely affect our business and financial condition.

The current global economic crisis described below should be considered when reviewing each of the subsequent paragraphs setting forth the various aspects of our business, operations, and products.

The recent global economic and financial market crisis has caused, among other things, a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and lower consumer and business spending. Although the ultimate outcome of these events cannot be predicted, it may have a material adverse effect on the Company and our ability to borrow money in the credit markets and potentially to draw on our revolving credit facility or otherwise obtain financing. Similarly, current or potential customers and suppliers may no longer be in business, may be unable to fund purchases or determine to reduce purchases, all of which could lead to reduced demand for our products, reduced gross margins, and increased customer payment delays or defaults. Further, suppliers may not be able to supply us with needed raw materials on a timely basis, may increase prices or go out of business, which could result in our inability to meet customer demand in a timely manner or affect our gross margins. We are also limited in our ability to reduce costs to offset the results of a prolonged or severe economic downturn given certain fixed costs associated with our operations.

We do a substantial amount of business with certain original equipment manufacturers (“OEM”) which as a group have produced substantial revenues for our Company. Loss of business from a major OEM customer will likely adversely affect our business.

Bovie manufactures the majority of its products on its premises in St. Petersburg, Florida. Labor-intensive sub-assemblies and labor-intensive products may be out-sourced to our specification. Although we sell through distributors, we market our products through national trade journal advertising, direct mail, distributor sales representatives and trade shows, under the Bovie name, the Bovie/Aaron name and private label. Major distributors include Allegiance (a Cardinal Company), IMCO, McKesson Medical Surgical, Inc., Medline, NDC (Abco, Cida and Starline), Owens & Minor, and Physician Sales & Service. If any of these distributor relationships are terminated or not replaced, our revenue from the territories served by these distributors could be adversely affected.

We have a major OEM customer, Arthrex, Inc. for which we manufacture products on a private label basis, pursuant to an agreement. On August 31, 2007, we amended and extended this manufacturing agreement for an additional three year period. The amended terms continue to provide that we will be reimbursed for our expenses in developing any changes or modifications to products according to Arthrex’s specifications, and Arthrex continues to own the intellectual property. In addition, general provisions for product warranties, insurance, termination, and confidentiality remain the same. The main change to the amended manufacturing agreement is the elimination of the provision that required Arthrex to exclusively purchase the products from us as well as the elimination of the provision that required us to forego competing in the same Arthrex markets with said products. This amended Arthrex Agreement has termination dates of December 6, 2010 and March 2011 for the generators. In fiscal 2008, Arthrex orders represented approximately 20% of our total revenues. As such, should Arthrex determine to reduce or cease placement of orders for the products, our business will likely be adversely affected.

We rely on certain suppliers and manufacturers for raw materials and other products and are vulnerable to fluctuations in the availability and price of such products and services.

We are also dependent on other OEM customers because we manufacture products for them; however they have no legal obligation to purchase such products. Should the collaborative customer fail to give us purchase orders for the product after development, our future business and value of related assets could be negatively affected. Furthermore, no assurance can be given that a collaborative customer will give sufficient high priority to our products. Finally, disagreements or disputes may arise between Bovie and its contractual customers, which could adversely affect production of our products. We also have informal collaborative arrangements with three foreign suppliers under which we request the development of certain items and components and we purchase them pursuant to purchase orders. Our purchase order commitments are never more than one year in duration and are supported by orders from our customers.

If we are unable to protect our patents or other proprietary rights, or if we infringe on the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged.

We have twenty patents and trademarks; however we do not believe the patents and trademarks have a material effect on our operations as their remaining useful lives are minimal. We can give no assurance that competitors will not infringe on our patent rights or otherwise create similar or non-infringing competing products that are technically patentable in their own right.

We have recently filed new patent applications for various new products including a scanning cannula, modular laparoscopic and endoscopic instruments, the output stage to our generator platform, our ICON product line and a Plasma Stream patent application relating to the plasma technology.

Although we carry liability insurance, due to the nature of our products and their use by professionals, we may, from time to time, be subject to litigation from persons who sustain injury during medical procedures in hospitals, physician’s offices or in clinics and defending such litigations is expensive, disruptive, time consuming and could adversely affect our business.

The manufacture and sale of medical products entail significant risks of product liability claims. Bovie currently maintains product liability insurance with combined coverage limits of $10 million on a claims made basis. There is no assurance that this coverage will be adequate to protect us from any possible liabilities we might incur in connection with the sale or testing of our products. In addition, we may need increased product liability coverage as products are commercialized. This insurance is expensive and in the future may not be available on acceptable terms, if at all.

Our manufacturing facilities are located in St. Petersburg, Florida and could be affected due to multiple risks from fire, hurricanes and the like.

Our manufacturing facilities are located in St. Petersburg, Florida and could be affected by multiple weather risks, most notably hurricanes (one of which previously caused damage to the roof of one of our buildings as well as some of our furniture and equipment). The damage was mildly disruptive to operations. Although we carry casualty insurance and business interruption insurance, future possible disruptions of operations due to hurricanes or other weather risks could affect our ability to meet our commitments to our customers and impair important business relationships, the loss of which could adversely affect our operations and profitability.

Risks Related to Our Industry

The medical device industry is highly competitive and we may be unable to compete effectively.

The medical device industry is highly competitive. Many competitors in this industry are well established, do a substantially greater amount of business, and have greater financial resources and facilities than we do.

Domestically, we believe we rank third in the number of units sold in the field of electrosurgical generator manufacturing and we sell our products and compete with other manufacturers in various ways. In addition to advertising, attending trade shows and supporting our distribution channels, we strive to enhance product quality, improve user friendliness and expand product exposure.

We also compete by private labeling our products for major distributors under their label. This allows us to increase our position in the marketplace and thereby compete from two different approaches, our Aaron or Bovie label, and our customers' private label. Our private label customers distribute our products under their name through their internal sales force. We believe our main competitors do not private label their products.

Lastly, at this time we sell the majority of our products through distributors. Many of the companies we compete with sell direct, thus competing directly with distributors they sometimes use.

Main competitors are Conmed, Valleylab (a division of Covidien) and Erbe Electromedizine, in the electrosurgery market, Xomed (a division of Medtronics), in the battery operated cautery market, Salient Surgical Technologies (formerly Tissuelink) in the saline enhanced sintered steel market and Ethicon and U.S. Surgical in the endoscopic instrumentation market. We believe our competitive position did not change in 2008.

Our industry is highly regulated by the U.S. Food and Drug Administration and internationally including other governmental, state and federal agencies which have substantial authority to establish criteria which must be complied with in order to continue in operation.

United States

The Company's products and research and development activities are subject to regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities:

- Product development.
- Product testing.
- Product labeling.
- Product storage.
- Pre-market clearance or approval.
- Advertising and promotion.
- Product traceability, and
- Product indications.

In the United States, medical devices are classified on the basis of control deemed necessary to reasonably ensure the safety and effectiveness of the device. Class I devices are subject to general controls. These controls include registration and listing, labeling, pre-market notification and adherence to the FDA Quality System Regulation. Class II devices are subject to general and special controls. Special controls include performance standards, post market surveillance, patient registries and FDA guidelines. Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness. Currently, we only manufacture Class I and Class II devices. Pre-market notification clearance must be obtained for some Class I and most Class II devices when the FDA does not require pre-market approval. All Bovie Medical products have been cleared by the Pre-market notification process. To date, the FDA has not failed to clear any devices we have submitted.

A pre-market approval application is required for most Class III devices. A pre-market approval application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device. The pre-market approval application typically includes:

- Results of bench and laboratory tests, animal studies, and clinical studies
- A complete description of the device and its components

- A detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling.

The pre-market approval process can be expensive, uncertain and lengthy. A number of devices for which pre-market approval has been sought by other companies have never been approved for marketing.

Manufacturing

Manufacturing and distribution of our products may be subject to continuing regulation by the FDA. We will also be subject to routine inspections by the FDA to determine compliance with the following:

- Quality system regulations.
- Medical device reporting regulations, and
- FDA restrictions on promoting products for unapproved or off-label uses.

In addition to regulations enforced by the FDA, we are also subject to regulations under the Occupational Safety and Health Act, the Environmental Protection Act and other federal, state and local regulations.

International Regulation

To market products in the European Union, our products must bear the "CE" mark. Manufacturers of medical devices bearing the CE mark have gone through a conformity assessment process that assures that products are manufactured in compliance with a recognized quality system and to comply with the European Medical Devices Directive.

Each device that bears a CE mark has an associated Technical File that includes a description of the following:

- Description of the device and its components,

. A summary of how the device complies with the essential requirements of the medical devices directive,
- Safety (risk assessment) and performance of the device,
- Clinical evaluations with respect to the device,
- Methods, facilities and quality controls used to manufacture the device, and
- Proposed labeling for the device.

Manufacturing and distribution of a device is subject to ongoing surveillance by the Notified Body to ensure continued compliance with quality system and reporting requirements.

We began CE marking of devices for sale in the European Union in 1999. In addition to the requirement to CE mark, each member country of the European Union maintains the right to impose additional regulatory requirements.

Outside of the European Union, regulations vary significantly from country to country. The time required to obtain approval to market products may be longer or shorter than that required in the United States or the European Union. Certain European countries outside of the European Union do recognize and give effect to the CE mark certification. We are permitted to market and sell our products in those countries.

If we are unable to successfully introduce new products or fail to keep pace with advances in technology, our business, financial condition and results of operations could be adversely affected. In addition, Our research and development efforts rely upon investments and alliances, and we cannot guarantee that any previous or future investments or alliances will be successful.

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Our research and development activities are an essential component of our efforts to develop new innovative products for introduction in the marketplace. New and improved products play a critical role in the Company's sales growth. The Company continues to place emphasis on the development of proprietary products and product improvements to complement and expand its existing product lines. We maintain close working relationships with physicians and medical personnel in hospitals and universities who assist in product research and areas of development. Our research and development activities are primarily developed internally and are expensed as incurred. These expenses include direct expenses for wages, materials and services associated with the development of our products net of any reimbursements from customers. Research and development expenses do not include any portion of general and administrative expenses. The Company has two complementary facilities that both contribute to a centralized research and development focus. Our St. Petersburg, FL facility has been our flagship research and design location, followed later by our addition of the Canadian facility in October 2006. Currently both facilities are working synergistically developing our new products the ICON GP/VS and ICON GS, as well as the accompanying Endoscopic Modular Instruments, the Polarian handle and accessories. We expect to make future investments to enable us to develop new technologies and products to further our strategic objectives and strengthen our existing business. However, we cannot guarantee that any of our previous or future investments will be successful.

The amount expended by us on research and development of our products during the years 2008, 2007 and 2006, totaled approximately $2.1, $1.6, and $1.0 million respectively. During the past three years, we invested in the J Plasma technology, currently used in one of our new products under development, the ICON GS plasma system. In addition, we invested in the SEER and BOSS devices, Endoscopic Modular Instruments and undertook development of Cardio and Urological Electrosurgical devices for a contractual partner. We have not incurred any direct costs relating to environmental regulations or requirements. For 2009 we expect our expenditures for research and development activities to remain around the same level as 2008.

Our international operations subject us to foreign currency fluctuations and other risks associated with operating in foreign countries.

We operate internationally and enter into transactions denominated in foreign currencies (most notably the Canadian dollar and the Euro). To date, we have not hedged our exposure to changes in foreign currency exchange rates, and as a result, we are subject to foreign currency transaction and translation gains and losses. We purchase goods and services in U.S. and Canadian dollars and have recently begun to invoice certain product sales in Euros. Foreign exchange risk is managed primarily by satisfying foreign denominated expenditures with cash flows or assets denominated in the same currency. We charged $88,464 to accumulated other comprehensive loss for the year ended December 31, 2008 as a result of changes in the relationship of the U.S. dollar to the Canadian dollar using the re-measurement method of translating our Canadian subsidiary's financial statements into U.S. dollars. Other foreign currency transaction gains amounted to $4,505.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Melville, New York on September 18, 2009.

Bovie Medical Corporation

By: /s/ ANDREW MAKRIDES
Andrew Makrides
President
Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
Principal Executive Officer:		
/s/ ANDREW MAKRIDES Andrew Makrides	Chief Executive Officer and Chairman of the Board	September 18, 2009
Principal Financial Officer:		
/s/ GARY D. PICKETT Gary D. Pickett	Chief Financial Officer, Treasurer, and Secretary	September 18, 2009
Directors:		
/s/ J. ROBERT SARON J. Robert Saron	President of Aaron Medical Industries, Inc. and Director	September 18, 2009
/s/ GEORGE KROMER George Kromer	Director	September 18, 2009
/s/ BRIAN MADDEN Brian Madden	Director	September 18, 2009
/s/ MICHAEL NORMAN Michael Norman	Director	September 18, 2009
/s/ AUGUST LENTRICCHIA August Lentricchia	Director	September 18, 2009
/s/ STEVE LIVNEH Steve Livneh	President of Bovie Canada and Director	September 18, 2009

/s/ STEVEN MACLAREN Steven MacLaren	Director	September 18, 2009
/s/ DR. PETER PARDOLL Dr. Peter Pardoll	Director	September 18, 2009

EXHIBIT INDEX

Exhibit 10.2*	Original Equipment Manufacturer Agreement between Arthrex, Inc. and Bovie Medical Corp. dated as of June, 2002.
Exhibit 10.11	Consulting and Intellectual Property Assignment Agreement dated January 12, 2006 among Bovie, Henvil Corp. Ltd and Steve Livneh
Exhibit 10.12*	Distribution Agreement between Bovie Medical Corporation and Boston Scientific dated October 6, 2006.
Exhibit 10.13*	First Amendment to Distribution Agreement between Boston Scientific Corporation and Bovie Medical Corporation August 23, 2007.
Exhibit 10.14*	Termination Purchase and License Agreement between Boston Scientific Corporation and Bovie Medical Corporation dated April 29, 2008.
Exhibit 10.15	Asset Purchase Agreement dated as of October 2, 2006 between Bovie Medical Corporation and Lican Developments, Ltd.
Exhibit 10.16*	First Amendment to Manufacturing and Development Agreement dated August 24, 2007 between Bovie Medical Corporation and Arthrex, Inc.
Exhibit 10.17	First Amendment to OEM Agreement between Arthrex, Inc. and Bovie Medical Corp. dated as of July, 2007
Exhibit 10.18	Amended Employment Agreement dated January 15, 2006 between Bovie Medical Corporation and Andrew Makrides
Exhibit 10.19	Amended Employment Agreement dated January 15, 2006 between J. Robert Saron and Bovie Medical Corporation
Exhibit 10.20	Amended Employment Agreement dated January 15, 2006 between Moshe Citronowicz and Bovie Medical Corporation
Exhibit 10.21	Employment Agreement dated June 18, 2007 between Bovie Medical Corporation and Gary Pickett.
Exhibit 10.22	Employment Agreement dated October 2, 2006 between Steve Livneh and Bovie Medical Corporation
Exhibit 10.23	Amendment to Consulting and Intellectual Property Assignment Agreement dated June 22, 2006 among Bovie, Henvil Corp. Ltd and Steve Livneh
Exhibit 31.1	Certification pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
Exhibit 31.2	Certification pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
Exhibit 32.1	Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
Exhibit 32.2	Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002.

* Subject to a confidential treatment application made by the Company simultaneously with this filing.