

ENCISION INC  
Form 10-K  
June 28, 2013  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended March 31, 2013

OR

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from            to

Commission File No.: 0-28604

**ENCISION INC.**

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(Exact name of registrant as specified in its charter)

**Colorado**  
(State or other jurisdiction  
of incorporation or organization)

**84-1162056**  
(I.R.S. Employer  
Identification No.)

**6797 Winchester Circle, Boulder, Colorado**  
(Address of principal executive offices)

**80301**  
(Zip Code)

Registrant's telephone number, including area code: **(303) 444-2600**

Securities registered under Section 12(b) of the Act: **Common Stock, no par value**

Securities registered under Section 12(g) of the 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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 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  (not required)

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.

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. (Check one):

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Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

As of September 28, 2012, the aggregate market value of the shares of common stock held by non-affiliates of the issuer on such date was \$3,946,785. This figure is based on the average bid and asked price of \$1.00 per share of the issuer's common stock on September 28, 2012 as quoted on the OTC Bulletin Board.

The number of shares outstanding of each of the issuer's classes of common equity, as of the last practicable date.

**Common Stock, no par value**  
(Class)

**8,210,100**  
May 31, 2013

Documents Incorporated by Reference: Definitive Proxy Statement for the 2013 Annual Shareholders Meeting to be filed with the Securities and Exchange Commission and incorporated by reference as described in Part III. The 2013 Proxy Statement will be filed within 120 days after the end of the fiscal year ended March 31, 2013.

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Table of Contents

Table of Contents

	<b>Page</b>
<u>PART I</u>	
<u>Item 1.</u> <u>Business</u>	2
<u>Item 1A.</u> <u>Risk Factors</u>	7
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	10
<u>Item 2.</u> <u>Properties</u>	10
<u>Item 3.</u> <u>Legal Proceedings</u>	10
<u>Item 4.</u> <u>(Removed and Reserved)</u>	10
<u>PART II</u>	
<u>Item 5.</u> <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	11
<u>Item 6.</u> <u>Selected Financial Data</u>	11
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	14
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	15
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	28
<u>Item 9A.</u> <u>Controls and Procedures</u>	28
<u>Item 9B.</u> <u>Other Information</u>	28
<u>PART III</u>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	29
<u>Item 11.</u> <u>Executive Compensation</u>	29
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	29
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	29
<u>Item 14.</u> <u>Principal Accounting Fees and Services</u>	29
<u>PART IV</u>	
<u>Item 15.</u> <u>Exhibits, Financial Statement Schedules</u>	29

Table of Contents

**Forward-Looking Statements**

Statements contained in this Annual Report on Form 10-K include forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve substantial risks and uncertainties that may cause actual results to differ materially from those indicated by the forward looking statements. All forward looking statements in this Annual Report on Form 10-K, including statements about our strategies, expectations about new and existing products, market demand, acceptance of new and existing products, technologies and opportunities, market size and growth, and return on investments in products and market, are based on information available to us on the date of this document, and we assume no obligation to update such forward looking statements. In some cases, you can identify forward looking statements by terminology such as may, will, should, could, expects, plans, intends, anticipates, believes, estimates, predicts, potential, or continue or the negative of such terms or other comparable terms. Readers of this Annual Report on Form 10-K are strongly encouraged to review the section entitled *Risk Factors*.

**PART I**

**Item 1. Business**

**Company Overview**

Encision Inc. ( Encision, we, us, our or the Company ), a medical device company based in Boulder, Colorado, has developed and markets innovative technology that provides unprecedented outcomes and patient safety in minimally-invasive surgery. We believe that our patented Active Electrode Monitoring® ( AEM ) Surgical Instruments are changing the marketplace for electro-surgical devices and laparoscopic instruments by providing a solution to a well-documented hazard unique to laparoscopic surgery.

We address market opportunities created by the increase in minimally-invasive surgery ( MIS ) and surgeons' use of electro-surgery devices in these procedures. The product opportunity exists in that monopolar electro-surgery instruments used in laparoscopic procedures provide excellent clinical results cost effectively, but are also susceptible to causing inadvertent collateral tissue damage outside the surgeon's field of view. The risk of unintended electro-surgical burn injury to the patient in laparoscopic surgery has been well documented. This risk poses a threat to patient safety, including the risk of death, and creates liability exposure for surgeons and hospitals, as well increased and preventable readmissions.

Our patented AEM technology provides surgeons with the desired tissue effects of cutting and coagulating tissue in laparoscopic procedures, while preventing stray electro-surgical energy that can cause complications and even death. AEM Surgical Instruments are equivalent to conventional instruments in size, shape, ergonomics and functionality, but they incorporate Active Electrode Monitoring technology to dynamically and continuously monitor the flow of electro-surgical current, thereby helping to prevent patient injury. With our shielded and monitored instruments, surgeons are able to perform electro-surgical procedures more safely, effectively and economically than is possible using conventional instruments.

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AEM technology has been recommended and endorsed by sources from many groups involved in MIS. Surgeons, nurses, biomedical engineers, the medicolegal community, malpractice insurance carriers and electro-surgical device manufacturers advocate the use of AEM technology.

### **Business Highlights**

#### *Proprietary, Patented Technology*

We have developed and launched patented AEM Surgical Instruments that enhance patient safety and patient outcomes in laparoscopic surgical procedures. We have been issued nine unexpired patents relating to AEM technology from the United States Patent and Trademark Office, each encompassing multiple claims, and which have between nine months and fifteen years seven months remaining. We also have patents relating to AEM technology issued in Europe, Japan, Canada and Australia.

#### *Technology Solves a Well-Documented Risk in Minimally Invasive Surgery*

MIS offers significant benefits for patients by reducing trauma, hospital stays, recovery times and medical costs. However, these benefits have not been achieved without the emergence of new risks. The risk of unintended tissue damage from stray electro-surgical energy has been well documented. Such injuries can be especially troubling given that often these injuries are out of the field of view, they can go unrecognized, and can lead to a cascade of adverse events, including death. Our patented AEM technology helps to eliminate the risk of stray electro-surgical burns in MIS while providing surgeons with the tissue effects they desire.

#### *Product Line has been Developed and Launched*

Our AEM Surgical Instruments have been engineered to provide a seamless transition for surgeons switching from conventional laparoscopic instruments. AEM technology has been integrated into instruments that have the same look, feel and functionality as conventional instruments that surgeons have been using for years. The AEM product line encompasses the full range of instrument sizes, types and styles favored by surgeons. Additionally we continued to improve quality and add to the product line, including more disposable versions, the introduction of hand-activated instruments, our enhanced scissors, the e Edge scissors, and the EM3 AEM Monitor, during our fiscal year ended March 31, 2013. Thus, hospitals can make a complete and smooth conversion to our product line, thereby advancing patient safety in MIS.

#### *Emerging as a Standard of Care*

We believe that AEM technology is following a similar path as previous technological developments in surgery. Throughout the history of electro-surgery, companies that have developed significant technological breakthroughs in patient safety have seen their technologies become widely used. As with Isolated electro-surgical generators in the 1970s and with REM technology in the 1980s, AEM technology is receiving the

Table of Contents

broad endorsements that drove these previous new technologies to becoming a standard of care. We believe that it is possible to follow a course similar to that of pulse oximetry in becoming a standard of care. Our proprietary AEM technology enhances patient safety in MIS, especially in light of laparoscopic instruments being in closer proximity with single-port and reduced-port approaches. As a result, clinicians are now advocating AEM technology's use.

***Developing Distribution Network is Advancing Utilization of AEM Technology***

Our AEM technology, in the hands of a sales network with broad access to the surgery marketplace, will help to increase utilization and market share. Historically, our sales and marketing efforts have been hindered by our small size and limited distribution channels. While these limitations continue, we have improved our sales network, which provided new hospital accounts with AEM technology in our fiscal year ended March 31, 2013. Our supplier agreements with Group Purchasing Organizations (GPOs) and other key hospitals systems, such as, Ascension are beginning to expose more hospitals to the benefits of our AEM technology.

**Market Overview**

We believe that our patented AEM technology provides us with marketing leverage toward gaining an increased share, both in terms of penetrations, as well as increasing our impact per procedure with AEM instrumentation. In our fiscal year ended March 31, 2013, AEM technology was used in 116,000 laparoscopic procedures.

In the 1990s, surgeons began widespread use of minimally-invasive surgical techniques. The benefits of MIS are substantial and include reduced trauma for the patient, reduced hospital stay, shorter recovery time and lower medical costs. With improvements in the surgical micro-camera and in the variety of available instruments, laparoscopic surgery became popular among general surgeons, gynecologic surgeons and other specialties. Laparoscopy now accounts for a large percentage of all surgical procedures performed in the United States. Approximately 75% of surgeons employ monopolar electrosurgery for laparoscopy according to INTERactive SURVEys. There are over 4.4 million laparoscopic procedures performed annually in the United States, and this number is increasing annually (Note: except as otherwise stated, market estimates in this section are as reported by Patient Safety & Quality Healthcare).

A component of the endoscopic surgery products market includes laparoscopic hand instruments, including scissors, graspers, dissectors, forceps, suction/irrigation devices, clip appliers and other surgical instruments of various designs, which provide a variety of tissue effects. Among the laparoscopic hand instruments, approximately \$400 million in sales annually are instruments designed for monopolar electrosurgical utility. This market for laparoscopic monopolar electrosurgical instruments is the market we are targeting with our innovative AEM Surgical Instruments. Our proprietary AEM product line supplants the conventional non-shielded, non-monitored electrosurgical instruments commonly used in laparoscopic surgery. In California, a jury awarded \$2.2 million on the basis of strict liability in a case involving a thermal injury against a competing medical device company. The verdict and award were affirmed by the California Court of Appeals on April 29, 2012.

When a hospital decides to use our AEM technology, we make recurring sales to such hospital for replacement instruments. Sales from replacement reusable and disposable AEM products in hospitals represented over 90% of our sales in the fiscal year ended March 31, 2013, and we expect this sales stream to grow as new hospitals increasingly adopt AEM technology and existing hospitals increase usage of AEM instrumentation. We also expect to increase the value per procedure delivered to our customers and, therefore, expect that the dollars per

procedure to increase. AEM Instruments are competitively priced compared to conventional laparoscopic instruments.

We aim to further develop the market by continuing to educate healthcare professionals about the benefits of AEM technology to advance patient safety. We are working to improve our sales network to reach the decision makers who purchase laparoscopic instruments and electro-surgical devices. We are also pursuing relationships with selected GPOs, hospital systems and integrated delivery networks to assist in promoting the benefits of AEM technology. As decisions are made at a system level, our intent is to highlight the clinical, economic and safety benefits of using AEM technology.

## **The Technology**

### ***Stray Electrosurgical Burn Injury to the Patient***

Electrosurgical technology is a valuable and popular resource for surgeons. Since its introduction in the 1930s, electrosurgical technology has continually evolved and is estimated to be used by over 75% of all laparoscopic general surgeons.

The primary form of electrosurgery, monopolar electrosurgery, is a standard tool for general surgeons throughout the world. In monopolar electrosurgery, the surgeon uses an instrument (typically scissors, grasper/dissectors, spatula blades or suction-irrigation electrodes) to deliver electrical current to patient tissue. This active electrode provides the surgeon with the ability to cut, coagulate or ablate tissue as needed during the surgery. With the advent of MIS procedures, surgeons have continued using monopolar electrosurgery as a primary tool for hemostatic incision, excision and ablation. Unfortunately, conventional laparoscopic electro-surgical instruments from competing manufacturers are susceptible to emitting stray electrical currents during the procedure. This risk is exacerbated by the fact that the micro-camera system used in laparoscopy limits the surgical field-of-view. Ninety percent of the instrument may be outside the surgeon's field-of-view at any given time during the surgery.

Because stray electrical current can occur at any point along the shaft of the instrument, the potential for burns occurring to tissue outside the surgeon's field-of-view is of great concern. Such burns to non-targeted tissue are dangerous as they are likely to go unnoticed and may lead to complications, such as perforation and infection in adjacent tissues or organs, and this can cause numerous adverse consequences. In many cases, the surgeon cannot detect stray electro-surgical burns at the time of the procedure. The resulting complication usually presents itself days later in the form of a severe infection, which often results in a return to the hospital and a difficult course of recovery for the patient. This situation has even resulted in fatalities.



Table of Contents

Stray electro-surgical burn injury can result from two causes – instrument insulation failure and capacitive coupling. Instrument insulation failure can be a common occurrence with laparoscopic instruments. Conventional active electrodes for laparoscopic surgery are designed with the same basic construction – a single conductive element and an outer insulation coating. Unfortunately, this insulation can fail during the course of surgery. One university study found insulation defects in disposable instruments right out of the package and even before use. It is also possible for instrument insulation to become flawed during the cleaning and sterilization process. This common insulation failure can allow electrical currents to “leak” from the instrument to unintended and unseen tissue with potentially serious ramifications for the patient, such as bowel perforations. Four different studies indicate that the insulation failure rate can be as high as one in five instruments. Capacitive coupling is another way stray electro-surgical energy can cause unintended burns during laparoscopy. Capacitive coupling is an electrical phenomenon that occurs when current is induced from the instrument to nearby tissue despite intact insulation. This potential for capacitive coupling is present in all laparoscopic surgeries that utilize monopolar electro-surgery devices and can likely occur outside the surgeon’s field-of-view.

Conventional, non-shielded, non-monitored laparoscopic instruments are susceptible to causing unintended, unseen burn injuries to the patient in MIS. Instrument insulation failure and capacitive coupling are the primary causes of stray electro-surgical burns in laparoscopy and are the two events over which the surgical team has traditionally had little, if any, control. Although alternative forms to monopolar electro-surgery energy exist, these alternative energies tend to be less effective, take longer to achieve the desired surgical effect and are considerably more costly.

***Encision’s AEM Surgical Instruments***

Active electrode monitoring technology can eliminate the risk of stray electrical energy caused by instrument insulation failure and capacitive coupling, and thus prevents unintended burn injury to the patient.

AEM Surgical Instruments are an innovative solution to stray electro-surgical burns in laparoscopic surgery and are designed with the same look, feel and functionality as conventional instruments. They direct electro-surgical energy where the surgeon desires, while continuously monitoring the current flow to prevent stray electro-surgical energy from instrument insulation failure or capacitive coupling.

Whereas conventional instruments are simply a conductive element with a layer of insulation coating, AEM Surgical Instruments have a patented, multi-layered design with a built-in shield, a concept much like the third-wire ground in standard electrical cords. The shield in these instruments is referenced back to a monitor at the electro-surgical generator. In the event of a harmful level of stray electrical energy, the monitor shuts down the power at the source, advancing patient safety. For instance, if instrument insulation failure should occur, the AEM system, while continually monitoring the instrument, immediately shuts down the electro-surgical generator, turning off the electrical current and alerting the surgical staff. The AEM system protects against capacitive coupling by providing a neutral return path for capacitively coupled electrical current. Capacitively coupled energy is continually drained away from the instrument and away from the patient through the protective shield built into all AEM instruments.

The AEM system consists of shielded 5mm AEM Instruments and an AEM monitor. The AEM Instruments are designed to function identically to the conventional 5mm instruments that surgeons are familiar with, but with the added benefit of enhanced patient safety. Our entire line of laparoscopic instruments has the integrated AEM design and includes the full range of instruments that are common in laparoscopic surgery today. The AEM monitor is compatible with most electro-surgical generators. AEM Surgical Instruments provide enhanced patient safety, require no change in surgeon technique and are cost competitive.

## Historical Perspective

We were organized as a Colorado corporation in 1991 and spent several years developing the AEM monitoring system and protective sheaths to adapt to conventional electrosurgical instruments. During this period, we conducted product trials and applied for patents with the United States Patent and Trademark Office and with International patent agencies. . Our patents relate to the basic shielding and monitoring technologies that we incorporate into our AEM products. As of March 31, 2013, we have nine unexpired United States patents relating to specific implementations of shielding and monitoring in instruments. Foreign patents relating to the core AEM shielding and monitoring technologies have been issued to us in Europe, Japan, Canada and Australia.

As we evolved, it was clear to us that our active electrode monitoring technology needed to be integrated into the standard laparoscopic instrument design. As the development program proceeded, it also became apparent that the merging of electrical and mechanical engineering skills in the instrument development process for our patented, integrated electrosurgical instruments was a complex and difficult task. As a result, instruments with integrated AEM technology were not completed for several years. Prior to offering a full range of laparoscopic electrosurgical instrumentation, it was difficult for hospitals to commit to the AEM solution, as we did not have adequate comparable surgical instrument options to match surgeon demand.

With the broad array of AEM instruments now available, the surgeon has a wide choice of instrument options and does not have to change surgical technique to use our AEM products. Since conversion to AEM technology is transparent to the surgeon, hospitals can now universally convert to AEM technology, thus providing all of their laparoscopic surgery patients a higher level of safety. This development coincides with the continued expansion of independent endorsements for AEM technology. Recommendations from the malpractice insurance and medicolegal communities complement the broad clinical endorsements that AEM technology has garnered over the past few years, leading to better awareness for the benefits of the technology.

## Products

We produce and market a full line of AEM Instruments, which are shielded and monitored to prevent stray electrosurgical burns from insulation failure and capacitive coupling. Our product line includes a broad range of articulating instruments (scissors, graspers and dissectors), fixed-tip electrodes and suction-irrigation electrodes. These AEM Instruments are available in a wide array of reusable and disposable options. Also, we have a line of handles that are used for advanced laparoscopic procedures that incorporate stiffer shafts and ergonomic features. In addition, we market an AEM monitor product line that is used in conjunction with AEM Instruments. During our fiscal year ended March 31, 2013 we

Table of Contents

introduced our enhanced scissors, the e Edge scissors, and the EM3 AEM Monitor. In addition, the company has launched a disposable fixed tip electrode and disposable suction-irrigation electrode products, both with hand control capabilities, to complement the EM3 AEM Monitor.

**Sales and Marketing Overview**

We believe that AEM technology can become the standard of care in laparoscopic surgery worldwide. Our marketing efforts are focused toward capitalizing on substantial independent endorsements for AEM technology. These third-party endorsements advocate utilizing active electrode monitoring for advancing patient safety in laparoscopic surgery. Substantial visibility has been achieved as a result of the technology's recognition as an *AORN Recommended Practice*.

In addition, there is increasing public interest in the reduction of medical errors and the advancement of patient safety. For example the National Quality Forum and CMS (Centers for Medicare and Medicaid Services) recognize patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility as a never-event. We believe that the credibility and importance of our technology is complemented by this expanding public interest in advancing patient safety.

To cost-effectively expand market coverage, we focus on optimizing our distribution network comprised of direct and independent sales representatives who are managed and directed by our regional sales managers throughout the United States. In some instances, customers have recognized the patient safety risks inherent in monopolar electrosurgery and have accepted AEM technology as the way to eliminate those risks. In other instances, we have found selling the concept behind AEM technology more difficult. This difficulty is due to several factors, including the necessity to make surgeons, nurses and hospital risk managers aware of the potential for unintended electrosurgical burns (which exists when conventional instruments are used during laparoscopic monopolar electrosurgery) and the resulting increased medicolegal liability exposure. Additionally, we must contend with the overall lack of single purchasing points in the industry (surgeons, hospital personnel, and value analysis committees have to be in substantial agreement as to the benefits of new technology), and the resulting need to make multiple sales calls on personnel with the authority to commit to hospital expenditures. Other challenges include the fact that many hospitals have exclusive contractual agreements with manufacturers of competing surgical instruments.

Our goal is to optimize a network that has experience selling into the hospital operating room environment. We believe that improvement in this network offers us the best opportunity to cost effectively broaden acceptance of our product line and generate increased and recurring sales. Additionally, we are pursuing supplier agreements with the major selected GPOs, hospital systems and integrated delivery networks.

In addition to the efforts to broaden market acceptance in the United States, we have contracted with independent distributors in Canada, Australia, New Zealand Japan and the Netherlands to market our products internationally. We have achieved Conformite Europeene ( CE ) marking for our products so that we may sell into the European marketplace. The CE marking indicates that a manufacturer has conformed to all of the obligations imposed by European health, safety and environmental legislation. While CE certification opens up incremental markets in Europe, our distribution options in the European marketplace are yet to be developed, and sales in international markets are negligible.

We believe that the expanding independent endorsements for AEM technology and the improved sales network of independent representatives will provide the basis for increased sales and continuing profitable operations. However, these measures, or any others that we may adopt, may not result in increased sales or profitable operations.

## **Research and Development**

We aim to continually expand our AEM Instrument product line to satisfy the evolving needs of surgeons. We employ full-time engineers and use independent contractors from time to time in our research and product development efforts. This group continuously explores ways to broaden and enhance the product line. Current research and development efforts are focused primarily on line-extension projects to further expand our AEM Instrument product offering to increase surgeons' choices and options in laparoscopic surgery. Our research and development expenses were \$1,755,894 in fiscal year 2013 and \$1,349,357 in fiscal year 2012. We expense research and development costs for products and processes as incurred. Costs that are included in research and development expenses include direct salaries, contractor fees, materials, facility costs and administrative expenses that relate to research and development.

## **Manufacturing, Regulatory Affairs and Quality Assurance**

We engage in various manufacturing and assembly activities at our leased facility in Boulder, Colorado. These operations include disposable scissor inserts manufacturing and assembly of our AEM Instrument system as well as fabrication, assembly and test operations for instruments and accessories. We also have relationships with a number of outside suppliers, including New Deantronics, Inc., who accounted for approximately 13% of our purchases in fiscal year 2013, who provide primary sub-assemblies, various electronic and sheet metal components, and molded parts used in our products.

We believe that the use of both internal and external manufacturing capabilities allows for increased flexibility in meeting our customer delivery requirements and significantly reduces the need for investment in specialized capital equipment. We have developed multiple sources of supply where possible. Our relationship with our suppliers is generally limited to individual purchase order agreements supplemented, as appropriate, by contractual relationships to help ensure the availability and low cost of certain products. All components, materials and sub-assemblies used in our products, whether produced in-house or obtained from others, are inspected to ensure compliance with our specifications. All finished products are subject to our quality assurance and performance testing procedures. During fiscal year 2013, we continued our manufacturing vertical integration goal with the addition of several processes and the addition of a controlled environment room to our manufacturing capabilities.

Table of Contents

As discussed in the section on Government Regulation, we are subject to the rules and regulations of the United States Food and Drug Administration ( FDA ). Our leased facility of 35,870 square feet contains approximately 15,100 square feet of manufacturing, regulatory affairs and quality assurance space. The facility is designed to comply with the Quality System Regulation ( QSR ), as specified in published FDA regulations. Our latest inspection by the FDA occurred in December 2012.

We achieved CE marking in August 2000, which required prior certification of our quality system and product documentation. Maintenance of the CE marking status requires periodic audits of the quality system and technical documentation by our European Notified Body, LGA InterCert. The most recent audit was completed in January 2010.

**Patents, Patent Applications and Intellectual Proprietary Rights**

We have invested heavily in an effort to protect our valuable technology, and, as a result of this effort, we have been issued nine unexpired relevant patents that together form a significant intellectual property position. Our patents relate to the basic shielding and monitoring technologies that we incorporate into our AEM products. As of March 31, 2013, we have nine unexpired United States patents relating to specific implementations of shielding and monitoring in instruments. Foreign patents relating to the core AEM shielding and monitoring technologies have been issued to us in Europe, Japan, Canada and Australia. As of March 31, 2013, there are between nine months and fifteen years seven months remaining on our AEM patents. We have seven patent applications in process and we have four trademarks.

Our technical progress depends to a significant degree on our ability to maintain patent protection for products and processes, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. Our policy is to attempt to protect our technology by, among other things, filing patent applications for technology that we consider important to the development of our business. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. Even though we hold patented technology, others might copy our technology or otherwise incorporate our technology into their products.

We require our employees to execute non-disclosure agreements upon commencement of employment. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's employment is our property and is to be kept confidential and not to be disclosed to third parties.

**Competition**

The electrosurgical device market is intensely competitive and tends to be dominated by a relatively small group of large and well-financed companies. We compete directly for customers with those companies that currently make conventional electrosurgical instruments. Larger competitors include Covidien Surgical Solutions Group (a division of Covidien Ltd.) and Ethicon Endo-Surgery (a division of Johnson & Johnson). While we know of no competitor (including those referenced above) that can provide a continuous solution to stray electrosurgical burns, the manufacturers of conventional (non-monitored, non-shielded) instruments will resist any loss of market share resulting from the presence of our products in the marketplace.

We also believe that manufacturers of products based on alternative technology to monopolar electrosurgery are our competitors. These alternative technologies include other energy technologies such as bipolar electrosurgery, laser surgery and the harmonic scalpel. Leading manufacturers in these areas include Covidien Surgical Solutions Group, Gyrus/ACMI (a division of Olympus Corporation and a leader in bi-polar electrosurgery), Lumenis (laser surgery) and Ethicon Endo-Surgery (a division of Johnson and Johnson, manufacturers of the harmonic scalpel). We believe that monopolar electrosurgery offers substantial competitive, functional and financial advantages over these alternative energy technologies and will remain the primary tool for the surgeon, as it has been for decades. However, the risk exists that these alternative technologies may gain greater market share and that new competitive techniques may be developed and introduced.

As mentioned in the Sales and Marketing discussion, the competitive issues involved in selling our AEM product line do not primarily revolve around a comparison of cost or features, but rather involve generating an awareness of the inherent hazards of electrosurgery and the potential for injury to the patient. This involves conceptual selling, rather than just a product selling, which results in a longer sales cycle and generally higher sales costs. Independent endorsements of AEM technology have greatly enhanced the credibility of AEM Instruments. However, our efforts to increase market awareness of this technology may not be successful, and our competitors may develop alternative strategies and/or products to counter our marketing efforts.

Many of our competitors and potential competitors have widely-used products and significantly greater financial, technical, product development, marketing and other resources. In addition to our direct sales force, we utilize a network of independent distributor representatives in selected areas. In some cases, our options for independent distribution have conflicting and competing product interests which compromise our ability to make market advances in certain areas. We may not be able to compete successfully against current and future competitors, and competitive pressures faced by us may have a material adverse impact on our business, operating results and financial condition.

#### **Government Regulation**

Government regulation in the United States and other countries is a significant factor in the development and marketing of our products and in our ongoing manufacturing, research and development activities. The FDA regulates us and our products under a number of statutes, including the Federal Food, Drug and Cosmetics Act (the FDC Act). Under the FDC Act, medical devices are classified as Class I, II or III on the basis of the controls deemed necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to the least extensive controls, as their safety and effectiveness can be reasonably assured through general controls (e.g., labeling, pre-market notification and adherence to QSR). For Class II devices, safety and effectiveness can be assured through the use of special controls (e.g., performance standards, post-market surveillance, patient registries and FDA guidelines). Class III devices (e.g., life-sustaining or life-supporting implantable devices or new devices which have been found not to be substantially equivalent to legally marketed devices) require the highest level of control, generally requiring pre-market approval by the FDA to ensure their safety and effectiveness.

Table of Contents

If a manufacturer or distributor of medical devices can establish that a proposed device is substantially equivalent to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not required a pre-market approval application, the manufacturer or distributor may seek FDA marketing clearance for the device by filing a 510(k) pre-market notification. Following submission of the 510(k) notification, the manufacturer or distributor may not place the device into commercial distribution in the United States until an order has been issued by the FDA. The FDA's target for issuing such orders is within 90 days of submission, but the process can take significantly longer. The order may declare the FDA's determination that the device is substantially equivalent to another legally marketed device and allow the proposed device to be marketed in the United States. The FDA may, however, determine that the proposed device is not substantially equivalent or may require further information, such as additional test data, before making a determination regarding substantial equivalence. Any adverse determination or request for additional information could delay market introduction and have a material adverse effect on our continued operations. We have received a favorable 510(k) notification for our AEM monitors and AEM Instruments, all of which are designated as Class II medical devices.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA also imposes post-marketing controls on us and our products, and registration, listing, medical device reporting, post-market surveillance, device tracking and other requirements on medical devices. Failure to meet these pervasive FDA requirements or adverse FDA determinations regarding our clinical and preclinical trials could subject us and/or our employees to injunction, prosecution, civil fines, seizure or recall of products, prohibition of sales or suspension or withdrawal of any previously granted approvals, which could lead to a material adverse impact on our financial position and results of operations.

The FDA regulates our quality control and manufacturing procedures by requiring us and our contract manufacturers to demonstrate compliance with the QSR as specified in published FDA regulations. The FDA requires manufacturers to register with the FDA, which subjects them to periodic FDA inspections of manufacturing facilities. If violations of applicable regulations are noted during FDA inspections of our manufacturing facilities or the facilities of our contract manufacturers, the continued marketing of our products may be adversely affected. Such regulations are subject to change and depend heavily on administrative interpretations. In December 2012, the FDA conducted a QSR inspection of our facilities. We believe that we have the internal resources and processes in place to be reasonably assured that we are in compliance with all applicable United States regulations regarding the manufacture and sale of medical devices. However, if we were found not to be in compliance with the QSR, in the future, such findings could result in a material adverse impact on our financial condition, results of operations and cash flows.

Sales of medical devices outside of the United States are subject to United States export requirements and foreign regulatory requirements. Legal restrictions on the sale of imported medical devices vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Our Certificate of Export from the United States Department of Health and Human Services expires August 2014. However, a specific foreign country in which we wish to sell our products may not accept or continue to accept the Certificate of Export. Entry into the European Economic Area market also requires prior certification of our quality system and product documentation. We achieved CE marking in August 2000, allowing a launch into the European marketplace. Maintenance of the CE marking status requires annual audits of the quality system and technical documentation by our European Notified Body, LGA InterCert. The most recent audit was completed in February 2013. In addition to licensing, entry into the Canadian market now requires quality system certification to ISO 13485:2003. Our quality system was audited and certification verified by LGA-InterCert of Nuremberg, Germany, in February 2013.

**Environmental Laws and Regulations**

From time to time we receive materials returned from customers, sales representatives and other sources which are potentially biologically hazardous. These materials are segregated, and disposed of in accordance with specific procedures that minimize potential exposure to

employees. The costs of compliance with these procedures are not significant. Our operations, in general, do not involve the use of environmentally sensitive materials.

### **Insurance**

We are covered under comprehensive general liability insurance policies, which have per occurrence and aggregate limits of \$1 million and \$2 million, respectively, and a \$5 million umbrella policy. We maintain customary property and casualty, workers' compensation, employer liability and other commercial insurance policies.

### **Employees**

As of March 31, 2013, we employed 60 full-time individuals, of which 13 are engaged directly in research, development and regulatory activities, 24 in manufacturing/operations, 17 in marketing and sales and 6 in administrative positions. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

### **Item 1A. Risk Factors**

You should carefully consider the risk factors described below. If any of the following risk factors actually occur, our business, prospects, financial condition or results of operations would likely suffer. In such case, the trading price of our common stock could fall, resulting in the loss of all or part of your investment. You should look at all these risk factors in total. Some risk factors may stand on their own. Some risk factors may affect (or be affected by) other risk factors. You should not assume we have identified these connections. You should not assume that we will always update these and future risk factors in a timely manner. We are not undertaking any obligation to update these risk factors to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

Among the factors that could cause future results and financial condition to be materially different from expectations are:



Table of Contents

*Our products may not be accepted by the market.* The success of our products and our financial condition depends on the acceptance of AEM products by the medical community in commercially viable quantities during fiscal year 2014 and beyond. We cannot predict how quickly or how broadly AEM products will be accepted by the medical community. We need to continually educate the marketplace about the potential hazards involved in the use of conventional electrosurgical products during MIS procedures and the expected benefits associated with the use of AEM products. If we are unsuccessful in educating the marketplace about our technology and the hazards of conventional instruments, we will not create sufficient demand by hospitals and surgeons for AEM products and our financial condition, results of operations and cash flows could be adversely affected.

*We need to continually develop and train our network of direct and independent sales representatives and expand our distribution efforts in order to be successful.* Our attempts to develop and train a network of direct and independent sales representatives in the U.S. and to expand our international distribution efforts may take longer than expected and may result in considerable amounts of retraining effort as the direct and independent sales representatives change their product lines, product focus and personnel. We may not be able to obtain full coverage of the U.S. by direct and independent sales representatives as quickly as anticipated. The independent sales representative network has inherent flaws and inefficiencies, which can include conflicts of interest and competing products. Optimizing the quality of the network and the performance of direct and independent sales representatives in the U.S. is an ongoing challenge. We may also encounter difficulties in developing our international presence due to regulatory issues and our ability to successfully develop international distribution options. Our inability to expand our network of direct and independent sales representatives and optimize their performance could adversely affect our financial results.

*We may need additional funding to support our operations.* We were formed in 1991 and have incurred losses of approximately \$17.2 million since that date. We have primarily financed research, development and operational activities with issuances of our common stock and warrants, the exercise of stock options to purchase our common stock, stock-based expense related to stock options and, in some years, by operating profits. At March 31, 2013, we had \$126,224 in cash available to fund future operations and, in addition, access to a line of credit for approximately \$997,000. We may find that investment in sales, marketing, research and development initiatives, merited by market opportunity, may result in our operating at a net loss from quarter to quarter. We may also find ourselves at a competitive disadvantage due to our constrained liquidity. On May 10, 2012, we signed an amendment to our credit facility agreement with Silicon Valley Bank, effective May 10, 2012. The terms of the credit facility include a line of credit for \$2,000,000 for two years at an interest rate calculated at the prime rate plus 1.25%, subject to increase upon a default. Our borrowing under the credit facility is limited by our eligible receivables and inventory at the time of borrowing. As of March 31, 2013, we had no borrowings from the credit facility and, under our eligible receivables and inventory limit, had an additional approximately \$997,000 available to borrow. The credit facility requires us to meet certain financial covenants. If we fail to comply with the restrictions contained in the credit facility and the lender does not waive such noncompliance, the resulting event of default could result in the lender accelerating the repayment of all outstanding amounts due under the credit facility or in our ability to receive additional funds under the credit facility. There can be no assurances that we would be successful in obtaining alternative sources of funding to repay these obligations should this event occur. In addition, should we need additional financing, we may not be able to obtain it on terms acceptable to us or at all.

*We may not be able to compete successfully against current manufacturers of conventional ( unshielded, unmonitored ) electrosurgical instruments or against competitors who manufacture products that are based on surgical technologies that are alternatives to monopolar electrosurgery.* The electrosurgical products market is intensely competitive. We expect that manufacturers of unshielded, unmonitored electrosurgical instruments will resist any loss of market share that might result from the presence of our shielded and monitored instruments in the marketplace. We also believe that manufacturers of products that are based upon surgical technologies that are alternatives to monopolar electrosurgery are our competitors. These technologies include bipolar electrosurgery, the harmonic scalpel and lasers. The alternative technologies may gain market share and new competitive technologies may be developed and introduced. Most of our competitors and potential competitors have significantly greater financial, technical, product development, marketing and other resources than we do. Most of our competitors also currently have substantial customer bases in the medical products market and have significantly greater market recognition than we have. As a result of these factors, our competitors may be able to respond more quickly to new or emerging technologies and changes in customer requirements or to devote greater resources to the development, promotion and sale of their products. It is possible that new competitors or new alliances among competitors may emerge and rapidly acquire significant market share. The competitive pressures we face may materially adversely affect our financial position, results of operations and cash flows, and this may hinder our ability to respond to competitive threats.

*If we do not continually enhance our products and keep pace with rapid technological changes, we may not be able to attract and retain customers.* Our future success and financial performance will depend in part on our ability to meet the increasingly sophisticated needs of customers through the timely development and successful introduction of product upgrades, enhancements and new products. These upgrades, enhancements and new products are subject to significant technological risks. The medical device market is subject to rapid technological change, resulting in frequent new product introductions and enhancements of existing products, as well as the risk of product obsolescence. While we are currently developing new products and enhancing our existing product lines, we may not be successful in completing the development of new products or enhancements. In addition, we must respond effectively to technological changes by continuing to enhance our existing products to incorporate emerging or evolving standards. We may not be successful in developing and marketing product enhancements or new products that respond to technological changes or evolving industry standards. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of those products, and our new products and product enhancements may not adequately meet the requirements of the marketplace and achieve commercially viable levels of market acceptance. If any potential new products, upgrades, or enhancements are delayed, or if any potential new products, upgrades, or enhancements experience quality problems or do not achieve market acceptance, or if new products make our existing products obsolete, our financial position, results of operations and cash flows would be materially adversely affected.

*If government regulations change or if we fail to comply with existing and/or new regulations, we might miss market opportunities and experience increased costs and limited growth.* The research, development, manufacturing, marketing and distribution of our products in the United States and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the Food and Drug Administration. Under the Federal Food, Drug and Cosmetic Act, medical devices must receive clearance from the Food and Drug Administration through the Section 510(k) pre-market notification process or through the more lengthy pre-market approval process before they can be sold in the United States. The process of obtaining required regulatory approvals is lengthy and has required the expenditure of substantial resources. There can be no assurance that we will be able to continue to obtain the necessary approvals. As part of our strategy, we also intend to

Table of Contents

pursue commercialization of our products in international markets. Our products are subject to regulations that vary from country to country. The process of obtaining foreign regulatory approvals in certain countries can be lengthy and require the expenditure of substantial resources. We may not be able to obtain necessary regulatory approvals or clearances on a timely basis or at all, and delays in receipt of or failure to receive such approvals or clearances, or failure to comply with existing or future regulatory requirements would have a material adverse effect on our financial position, results of operations and cash flows.

*If we fail to comply with the extensive regulatory requirements governing the manufacturing of our products, we could be subject to fines, suspensions or withdrawals of regulatory approvals, product recalls, suspension of manufacturing, operating restrictions and/or criminal prosecution.* The manufacturing of our products is subject to extensive regulatory requirements administered by the Food and Drug Administration and such other regulatory agencies. Inspection of our manufacturing facilities and processes can be conducted at any time, without prior notice, by the Food and Drug Administration and such regulatory agencies. In addition, future changes in regulations or interpretations made by the Food and Drug Administration or other regulatory agencies, with possible retroactive effect, could adversely affect us. Changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. We may not be able to obtain necessary regulatory approvals or clearances on a timely basis in the future, or at all. Delays in receipt of, failure to receive such approvals or clearances and/or failure to comply with existing or future regulatory requirements would have a material adverse effect on our financial position, results of operations and cash flows.

*Our current patents, trade secrets and know-how may not provide a competitive advantage, the pending applications may not result in patents being issued, and our competitors may design around any patents issued to us.* Our success will continue to depend in part on our ability to maintain patent protection for our products and processes, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. We have nine issued U.S. patents on several technologies embodied in our AEM Monitoring System, AEM Instruments and related accessories and we have applied for additional U.S. patents. In addition, we have four issued foreign patents. The validity and breadth of claims coverage in medical technology patents involve complex legal and factual questions and may be highly uncertain. Also, patents may not protect our proprietary information and know-how or provide adequate remedies for us in the event of unauthorized use or disclosure of such information, and others may be able to develop competing technology, independent of such information. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us, to defend us against claimed infringement of the rights of others or to determine the ownership, scope or validity of our proprietary rights or those of others. Any such claims may require us to incur substantial litigation expenses and to divert substantial time and effort of management personnel and could substantially decrease the amount of capital available for our operations. An adverse determination in litigation involving the proprietary rights of others could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, and could prevent us from manufacturing, selling or using our products. The occurrence of any such actual or threatened litigation or the effect on our business of such litigation may materially adversely affect our financial position, results of operations and cash flows. Additionally, our assessment that a patent is no longer of value could result in a significant charge against our earnings.

*We depend on single source suppliers for certain of the key components of our products and sub-contractors to provide much of the materials used in the manufacturing of our products. The loss of a supplier or limitation in supply from existing suppliers could have a material adverse effect on our ability to manufacture our products until a new source of supply is located.* Although we believe that there are alternative suppliers, any interruption in the supply of key components could have a material adverse effect on us. A sudden increase in customer demand may create a backorder situation as lead times for some of our critical materials are in excess of 12 weeks. We rely on subcontractors to provide products, either in the form of finished goods or sub-assemblies that we then assemble and test. While these sub-contractors reduce our total cost of manufacturing, they may not be as responsive to increased demand as we would be if we had our manufacturing capacity entirely in-house, which may limit our growth strategy and sales.

*The potential fluctuation in future quarterly results may cause our stock price to fluctuate.* We expect that our operating results could fluctuate significantly from quarter to quarter in the future and will depend upon a number of factors, many of which are outside our control. These factors include the extent to which our AEM technology and related accessories gain market acceptance; our investments in marketing, sales, research

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and development and administrative personnel necessary to support growth; our ability to expand our market share; actions of competitors; and, general economic conditions. The market value of our common stock has dramatically fluctuated in the past and is likely to fluctuate in the future. Any of these factors, or factors not listed, could have an immediate and significant negative impact on the market price of our stock.

*Our common stock is thinly traded, the prices at which it trades are volatile and the buying or selling actions of a few shareholders may adversely affect our stock price.* As of April 30, 2013, we had a public float, which is defined as shares outstanding minus shares held by our officers, directors, or beneficial holders of greater than 5% of our outstanding common stock, of 3,946,785 shares, or 48.1% of our outstanding common stock. The average number of shares traded in any given day over the past year has been relatively small compared to the public float. Thus, the actions of a few shareholders either buying or selling shares of our common stock may adversely affect the price of the shares. Historically, thinly-traded securities such as our common stock have experienced extreme price and volume fluctuations that do not necessarily relate to operating performance.

*Product liability claims may exceed our current insurance coverage.* We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects to a patient. We maintain a general liability insurance policy up to the amount of \$5,000,000 that includes coverage for product liability claims. Liability claims may be excluded from the policy, may exceed the coverage limits of the policy, or the insurance may not continue to be available on commercially reasonable terms or at all. Consequently, a product liability claim or other claim with respect to uninsured liabilities or in excess of insured liabilities could have a material adverse effect on our financial position, results of operations and cash flows.

*We depend on certain key personnel.* We are highly dependent on a limited number of key management personnel, particularly our President and CEO, Fred F. Perner. Our loss of key personnel to death, disability or termination, or our inability to hire and retain qualified personnel, could have a material adverse effect on our financial position, results of operations and cash flow.

Table of Contents

**Item 1B. Unresolved Staff Comments**

Not required for small reporting companies.

**Item 2. Properties**

We lease 35,870 square feet of office and manufacturing space under noncancelable lease agreements through July 31, 2014 at 6797 Winchester Circle, Boulder, Colorado. We believe that our existing facilities are adequate for our current operations.

**Item 3. Legal Proceedings**

We are involved in two legal proceeding that arose in the normal course of business. One legal proceeding relates to a product that we manufacturer. The other legal proceeding relates to a product of another manufacturer that was not distributed by nor associated in any way with us, but we were included as one of the defendants in the proceeding. These matters are product liability actions. We do not know whether we will prevail in these matters nor can we assure that any remedy could be reached on commercially viable terms, if at all. Based on currently available information, we believe that we have meritorious defense to these actions and that the resolution of these cases is not likely to have a material adverse effect on our business, financial position or future results of operations. In accordance with generally accepted accounting principles in the United States (U.S. GAAP), we record a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impacts of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to a particular case.

**Item 4. (Removed and Reserved)**

Table of Contents**PART II****Item 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock has been quoted on the Pink Sheets Electronic Quotation Service ( Pink Sheets ) maintained by Pink Sheets LLC for the National Quotation Bureau, Inc. The ticker symbol ECIA has been assigned to our common stock for over-the-counter quotations. The following table shows the range of high and low bid quotations for each share of our common stock on the Pink Sheets, as applicable, for the periods indicated. The bid quotations on the Pink Sheets reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Fiscal	2013				2012			
	High	Low	High	Low	High	Low	High	Low
First quarter	\$ 1.85	\$ 0.91	\$ 1.40	\$ 0.96				
Second quarter	\$ 1.34	\$ 0.81	\$ 1.23	\$ 0.75				
Third quarter	\$ 1.24	\$ 0.74	\$ 1.50	\$ 0.94				
Fourth quarter	\$ 1.98	\$ 1.14	\$ 1.20	\$ 0.93				

We have never paid cash dividends on our common stock and have no present plans to do so. We presently intend to retain any cash generated from operations in the future for use in our business. As of March 31, 2013, there were approximately 94 holders of record of our common stock.

**Item 6. Selected Financial Data**

Not required for smaller reporting companies.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

Certain statements contained in this section are not historical facts, including statements about our strategies and expectations about new and existing products, market demand, acceptance of new and existing products, technologies and opportunities, market and industry segment growth, and return on investments in products and markets. These statements are forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve substantial risks and uncertainties that may cause actual results to differ materially from those indicated by the forward looking statements. All forward looking statements in this section are based on information available to us on the date of this document, and we assume no obligation to update such forward looking statements. Readers of this Form 10-K are strongly encouraged to review the section entitled *Risk Factors* .

**Outlook**

*Installed Base of AEM Monitoring Equipment.* We believe that we are gaining more awareness in medico-legal circles and publications and from presentations at medical meetings. We believe that improvement in the quality of sales representatives carrying AEM product line, along with increased marketing efforts and the introduction of new products, may provide the basis for increased sales and continuing profitable operations. However, these measures, or any others that we may adopt, may not result in either increased sales or continuing profitable operations.

*Possibility of Operating Losses.* We have an accumulated deficit of \$17,175,693 at March 31, 2013. We have made significant strides toward improving our operating results. However, due to the ongoing need to develop new products, the need to develop, optimize and train our sales distribution network and the need to increase sustained sales to a level adequate to cover fixed and variable operating costs, we may operate at a net loss.

*Sales Growth.* We expect to generate increased sales in the U.S. from sales to new hospital customers and to grow AEM instrumentation sales to existing accounts. In fiscal year 2014, we will focus on regrowing our AEM franchise through a campaign focused on the clinical, economic and safety benefits of AEM technology, a medico-legal initiative and our new AEM products. In addition, prior years' efforts in vertical integration have given us three core competencies—electrosurgery, instrument design, and manufacturing—which we expect will allow us to increase sales from our strategic partnership initiatives. Our goal is to offer our customers an AEM disposable counterpart for each AEM reusable instrument.

*Gross Margin.* We believe that our fiscal year 2014 gross margin will increase due to a higher gross margin on product revenue as a result of an increase in product produced.

*Sales and Marketing Expenses.* We continue our efforts to expand domestic and international distribution capability, and we believe that sales and marketing expenses will need to be maintained at a healthy level in order to expand our market visibility and optimize the field sales capability of converting new hospital customers to AEM technology. Sales and marketing expenses are expected to increase as we increase our marketing efforts to support our direct sales representatives. In fiscal year 2014, we expect to have 13 direct sales territories and three direct sales managers. Each direct sales manager also manages a separate territory.

*Manufacturing.* We believe that we will be able to achieve cost reductions, and provide better control over quality and consistency, by producing products on our own. We manufacture our own disposable scissor inserts and are exploring other products that we may manufacture on our own.

*Research and Development Expenses.* Research and development expenses are expected to increase to support development of refinements to our AEM product line, which will further expand the instrument options for the surgeon. New refinements to AEM product line are planned for introduction in fiscal year 2014.

Table of Contents

**Results of Operations**

*Product Revenue.* Our product revenue for the fiscal year ended March 31, 2013 ( FY 13 ) was \$11,216,100, and for the fiscal year ended March 31, 2012 ( FY 12 ) our product revenue was \$11,225,653. This represents a slight decrease of \$9,553 in FY 13 from FY 12. The decrease is attributable to business lost from hospitals that stopped or reduced using AEM technology. This was partially offset by 22 new hospital accounts for AEM technology, which increased the installed base of users of reusable and disposable AEM Surgical Instruments.

*Service Revenue.* Our service revenue for the fiscal year ended March 31, 2013 ( FY 13 ) was \$550,469, and for the fiscal year ended March 31, 2012 ( FY 12 ) was \$1,762,997. This represents a decrease of \$1,212,528 in FY 13 from FY 12. The decrease is a result of a project that has been phased out by a strategic partner. As a result, and unless we obtain another strategic partner or further commitments from existing partners, we anticipate that future service revenue will be significantly reduced as compared to last fiscal year's service revenue. Service revenue represents design and development services.

*Gross profit.* Product gross profit in FY 13 of \$6,447,589 represented an increase of 6% from product gross profit of \$6,078,095 in FY 12, which resulted in a product gross margin of 57.5% of net product revenue for FY 13 and 54% of net product revenue for FY 12. The gross profit margin increase from FY 12 was due to gross margins that were lower in FY 12 due to a one-time charge of \$430,000 for a voluntary recall of certain electrode product. The increase in FY 13 was partially reduced by higher material costs and higher unit overhead costs. Service gross profit in FY 13 of \$87,230 represented a decrease of \$859,693 from service gross profit of \$946,923 in FY 12 as a result of lower service revenue volume.

*Sales and marketing expenses.* Sales and marketing expenses were \$3,617,206 in FY 13, a decrease of \$711,951, or 16%, from \$4,329,157 in FY 12. The decrease was the result of reduced compensation as a result of reduced direct sales representatives, lower general purchasing organizations' fees due to ceasing our relationships with some of our general purchasing organizations, and reduced sales samples and travel and meals.

*General and administrative expenses.* General and administrative expenses were \$1,711,267 in FY 13, a decrease of \$107,589, or 6%, from \$1,818,856 in FY 12. The decrease was the result of reduced compensation expense, principally due to compensation expense for severance cost that was incurred in FY 12, reduced board of directors' and investor relations' fees, reduced sales samples and temporary contractor costs. The decrease was partially offset by increased outside service costs and software costs.

*Research and development expenses.* Research and development expenses were \$1,755,894 in FY 13, an increase of \$406,537 or 30%, from \$1,349,357 in FY 12. The increase was the result of an increase in compensation and outside services, especially for quality efforts and development of new products, an increase to facilities allocation for additional space, inventory usage and reduced internal resource cost allocation to service revenue cost of revenue due to reduced service revenue. The net increase was partially reduced by decreased temporary help and consulting fees.

*Other income and expense, net.* Other income and expense, net includes \$63,808 for the medical device excise tax in FY 13.



*Net loss.* Net loss in FY 13 of \$615,673 represented an increase of \$85,020 compared to FY 12 net loss of \$530,653. The net loss was primarily the result of reduced service revenue. The net loss increase was partially offset by a higher gross profit margin, reduced operating expenses, as discussed above, and reduced interest expense.

### **Liquidity and Capital Resources**

To date, operating funds have been provided primarily by issuances of our common stock and warrants, the exercise of stock options to purchase our common stock and, in some years, by operating profits. To date, common stock and additional paid in capital totaled \$21,569,993 from our inception through March 31, 2013. Our operations used \$315,793 and provided \$159,635 of cash in FY 13 and FY 12, respectively, on revenue of \$11,766,569 and \$12,988,650 in FY 13 and FY 12, respectively. These amounts of cash generated from operations are not indicative of the expected cash to be generated from or used by operations in the fiscal year ending March 31, 2014 ( FY 14 ). As of March 31, 2013, we had \$126,224 in cash and cash equivalents, and under our eligible receivables and inventory limit, had an additional approximately \$997,000 available under our credit facility to fund future operations. Working capital was \$2,518,553 at March 31, 2013 compared to \$2,837,788 at March 31, 2012. The decrease in working capital was caused, principally, by a reduction of cash. Current liabilities were \$1,588,634 at March 31, 2013, compared to \$1,672,425 at March 31, 2012. The decrease in current liabilities at March 31, 2013 was caused, principally, by a decrease in accounts payable and was partially offset by an increase to other accrued liabilities.

On May 10, 2012, we signed an amendment to our credit facility agreement with Silicon Valley Bank, effective May 10, 2012. The terms of the credit facility include a line of credit for \$2,000,000 for two years at an interest rate calculated at the prime rate plus 1.25%, subject to increase upon a default. Our borrowing under the credit facility is limited by our eligible receivables and inventory at the time of borrowing. As of March 31, 2013 we had no borrowings from the credit facility. As of March 31, 2013, under our eligible receivables and inventory limit, we had an additional approximately \$997,000 available to borrow. Our credit facility agreement requires us to meet certain financial covenants. During our quarter ended June 30, 2013, we failed to meet the minimum defined quick debt ratio covenant. As a result, the lender may impose a monthly maintenance fee, require additional financial reporting and restricts our borrowings to the beginning of each week instead of when needed.

We believe that the unique performance of AEM technology and our breadth of independent endorsements provide an opportunity for market share growth. We believe that the market awareness of AEM technology and its endorsements is continually improving and that this will benefit revenue efforts in FY 14. We believe that we enter FY 14 having achieved improvements in the clinical credibility of our technology. Our FY 14 operating plan is focused on growing revenue, increasing gross profits, increasing research and development costs while increasing profits and positive cash flows. We cannot predict with certainty the expected revenue, gross profit, net income or loss and usage of cash and cash equivalents for FY 14. We believe that cash resources and borrowing capacity will be sufficient to fund our operations for at least the next twelve months under our current operating plan. If we are unable to manage business operations in line with our budget expectations, it could have a material adverse effect on business viability, financial position, results of operations and cash flows. Further, if we are not successful in sustaining profitability and remaining at least cash flow break-even, additional capital may be required to maintain ongoing operations.

Table of Contents

We have explored and are continuing to explore options to provide additional financing to fund future operations as well as other possible courses of action. Such actions include, but are not limited to, securing a larger credit facility, sales of debt or equity securities (which may result in dilution to existing shareholders), licensing of technology, strategic alliances and other similar actions. There can be no assurance that we will be able to obtain additional funding (if needed) through a sale of our common stock or loans from financial institutions or other third parties or through any of the actions discussed above on terms acceptable to us or at all. If we cannot sustain profitable operations and additional capital is unavailable, lack of liquidity could have a material adverse effect on our business viability, financial position, results of operations and cash flows.

**Income Taxes**

As of March 31, 2013, net operating loss carryforwards totaling approximately \$7.7 million were available to reduce taxable income in the future. The net operating loss carryforwards expire, if not previously utilized, at various dates beginning in fiscal year 2019. We have not paid income taxes since our inception. The Tax Reform Act of 1986 and other income tax regulations contain provisions which may limit the net operating loss carryforwards available to be used in any given year if certain events occur, including changes in our ownership. We have established a valuation allowance for the entire amount of our deferred tax asset since inception due to our history of losses. Should we achieve sufficient, sustained income in the future, we may conclude that some or all of the valuation allowance should be reversed.

**Off-Balance Sheet Financing Arrangements**

Except as described below, we do not utilize variable interest entities or other off-balance sheet financial arrangements.

We have a commitment under an operating lease for manufacturing equipment with General Electric Capital Corporation. Lease expense under this arrangement for the fiscal years ended March 31, 2013 and 2012 was \$101,873 and \$101,873, respectively.

We have a commitment for our facility at 6797 Winchester Circle, Boulder, Colorado. Rent expense for our facilities for the fiscal years ended March 31, 2013 and 2012 was \$293,830 and \$263,597, respectively

**Contractual Obligations**

We currently lease 35,870 square feet of office and manufacturing space at our facilities at 6797 Winchester Circle, Boulder, Colorado under noncancelable lease agreements through July 31, 2014. The minimum total future lease payment, by fiscal year, as of March 31, 2013 is as follows:

<b>Fiscal Year</b>	<b>Amount</b>
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2014	\$	320,080
2015		108,303
<b>Total</b>	<b>\$</b>	<b>428,383</b>

Our minimum future equipment lease payments with General Electric Capital Corporation as of March 31, 2013, by fiscal year, are as follows:

<b>Fiscal Year</b>		<b>Amount</b>
2014	\$	8,488

On May 10, 2012, we signed an amendment to our credit facility agreement with Silicon Valley Bank, effective May 10, 2012. The terms of the credit facility include a line of credit for \$2,000,000 for two years at an interest rate calculated at the prime rate plus 1.25%, subject to increase upon a default. Our borrowing under the credit facility is limited by our eligible receivables and inventory at the time of borrowing. The credit facility is secured by all tangible and intangible assets, whether now owned or hereafter acquired, wherever located.

As of March 31, 2013, the following table shows our contractual obligations for the periods presented:

Contractual obligations	Totals	Payment due by period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	436,871	328,568	108,303		

Aside from the operating lease and credit facility commitments, we do not have any material contractual commitments requiring settlement in the future.

### Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, sales and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to bad debts, inventories, sales returns, warranty, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our financial statements.

Table of Contents

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required, which would increase our expenses during the periods in which any such allowances were made. The amount recorded as a provision for bad debts in each period is based upon our assessment of the likelihood that we will be paid on our outstanding receivables, based on customer-specific as well as general considerations. To the extent that our estimates prove to be too high, and we ultimately collect a receivable previously determined to be impaired, we may record a reversal of the provision in the period of such determination.

We provide for the estimated cost of product warranties at the time sales are recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our component suppliers, we have experienced some costs related to warranty. The warranty accrual is based upon historical experience and is adjusted based on current experience. Should actual warranty experience differ from our estimates, revisions to the estimated warranty liability would be required.

We reduce inventory for estimated obsolete or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Any write-downs of inventory would reduce our reported net income during the period in which such write-downs were applied.

We recognize deferred income tax assets and liabilities for the expected future income tax consequences, based on enacted tax laws, of temporary differences between the financial reporting and tax bases of assets and liabilities. Deferred tax assets are then reduced, if deemed necessary, by a valuation allowance for the amount of any tax benefits which, more likely than not based on current circumstances, are not expected to be realized. Should we achieve sufficient, sustained income in the future, we may conclude that all or some of the valuation allowance should be reversed.

Property and equipment are stated at cost, with depreciation computed over the estimated useful lives of the assets, generally three to seven years. We use the straight-line method of depreciation for property and equipment. Leasehold improvements are depreciated over the shorter of the remaining lease term or the estimated useful life of the asset. Maintenance and repairs are expensed as incurred and major additions, replacements and improvements are capitalized.

We amortize our patent costs over their estimated useful lives, which is typically the remaining statutory life. From time to time, we may be required to adjust these lives based on advances in technology, competitor actions, and the like. We review the recorded amounts of patents at each period end to determine if their carrying amount is still recoverable based on our expectations regarding sales of related products. Such an assessment, in the future, may result in a conclusion that the assets are impaired, with a corresponding charge against earnings.

Stock-based compensation is presented in accordance with the guidance of Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Topic 718, Compensation - Stock Compensation ( ASC 718 ). Under the provisions of ASC 718, companies are required to estimate the fair value of share-based payment awards made to employees and directors including employee stock options based on estimated fair values on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our statement of operations.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not required.

Table of Contents

**Item 8. Financial Statements and Supplementary Data**

The following financial statements are included in this Report:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	16
<u>Balance Sheets as of March 31, 2013 and 2012</u>	17
<u>Statements of Operations for the fiscal years ended March 31, 2013 and 2012</u>	18
<u>Statements of Shareholders' Equity for the fiscal years ended March 31, 2013 and 2012</u>	19
<u>Statements of Cash Flows for the fiscal years ended March 31, 2013 and 2012</u>	20
<u>Notes to Financial Statements</u>	21

Table of Contents

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of

Encision Inc.

Boulder, Colorado

We have audited the accompanying balance sheets of Encision Inc. (the Company) as of March 31, 2013 and 2012 and the related statements of operations, shareholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Encision Inc. as of March 31, 2013 and 2012, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eide Bailly LLP

Greenwood Village, Colorado  
June 28, 2013

Table of Contents**Encision Inc.****Balance Sheets**

	<b>March 31, 2013</b>	<b>March 31, 2012</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 126,224	\$ 564,671
Accounts receivable, net of allowance for doubtful accounts of \$9,000 at March 31, 2013 and \$15,500 at March 31, 2012	985,770	1,427,966
Inventories, net of reserve for obsolescence of \$51,000 at March 31, 2013 and \$117,000 at March 31, 2012	2,929,302	2,489,008
Prepaid expenses	65,891	28,568
<b>Total current assets</b>	<b>4,107,187</b>	<b>4,510,213</b>
Equipment, at cost:		
Furniture, fixtures and equipment	2,691,057	2,497,471
Customer-site equipment	931,060	819,403
Equipment-in-progress	774,004	777,839
Accumulated depreciation	(2,767,195)	(2,476,004)
Equipment, net	1,628,926	1,618,709
Patents, net of accumulated amortization of \$190,770 at March 31, 2013 and \$169,084 at March 31, 2012	237,606	272,714
Other assets	9,215	7,415
<b>TOTAL ASSETS</b>	<b>\$ 5,982,934</b>	<b>\$ 6,409,051</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 823,347	\$