

ENCISION INC
Form 10KSB
June 30, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-KSB

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

For the fiscal year ended March 31, 2008

OR

**o 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.

(Name of small business issuer in its charter)

Colorado
(State of incorporation)

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

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

80301
(Zip Code)

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

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

Name of exchange on which registered: **American Stock Exchange**

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

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

Check whether the issuer (1) 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 x No o**

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. **x**

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

The issuer's revenues for fiscal year ended **March 31, 2008** was **\$12,065,659**

As of May 30, 2008, the aggregate market value of the shares of common stock held by non-affiliates of the issuer on such date was \$6,675,352. This figure is based on the closing sales price of \$2.30 per share of the issuer's common stock on May 30, 2008.

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)

6,455,100
(Outstanding at May 30, 2008)

Transitional Small Business Disclosure Format Yes **o** No **x**

Documents Incorporated by Reference: Definitive Proxy Statement for the 2008 Annual Shareholders Meeting to be filed with the Securities and Exchange Commission and incorporated by reference as described in Part III. The 2008 Proxy Statement will be filed within 120 days after the end of the fiscal year ended March 31, 2008.

Statements contained in this Annual Report on Form 10-KSB 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 the Annual Report on Form 10-KSB, 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-KSB 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 launched innovative technology that is emerging as a standard of care in minimally-invasive surgery. We believe that our patented AEM® Surgical Instruments are changing the marketplace for electrosurgical devices and laparoscopic instruments by providing a solution to a well-documented patient safety risk in laparoscopic surgery.

We were founded to address market opportunities created by the increase in minimally-invasive surgery (MIS) and surgeons' use of electrosurgery devices in these procedures. The product opportunity was created by surgeons' widespread demand to use monopolar electrosurgery instruments, which, when used in laparoscopic surgery, are susceptible to causing inadvertent collateral tissue damage outside the surgeon's field of view. The risk of unintended electrosurgical burn injury to the patient in laparoscopic surgery has been well documented. This risk poses a threat to patient safety and creates liability exposure for surgeons and hospitals.

Our patented AEM technology provides surgeons with the desired tissue effects, while preventing stray electrosurgical energy that can cause unintended and unseen tissue injury. AEM Laparoscopic 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 electrosurgical current, thereby helping to prevent patient injury. With our shielded and monitored instruments, surgeons are able to perform electrosurgical procedures more safely and effectively than is possible using conventional instruments. In addition, the AEM instruments are cost competitive with conventional non-shielded, non-monitored instruments. The result is advanced patient safety at comparable cost and with no change in surgeon technique.

AEM technology has been recommended and endorsed by sources from all groups involved in MIS. Surgeons, nurses, biomedical engineers, the medicolegal community, malpractice insurance carriers and electrosurgical device manufacturers advocate the use of AEM technology. The breadth of endorsements continues to expand with the recognition of active electrode monitoring technology as an *AORN Recommended Practice for Electrosurgery* and *AORN Recommended Practice for Minimally-Invasive Surgery* by the Association of periOperative Registered Nurses (AORN). Additionally, a recommendation was made by a hospital malpractice insurance carrier that hospitals use surgical instruments which incorporate shielding and monitoring technology.

Business Highlights

Proprietary, Patented Technology

We have developed and launched patented AEM Surgical Instruments that enhance patient safety and patient outcome in laparoscopic surgical procedures. We have been issued four patents relating to AEM technology from the United States Patent and Trademark Office, each encompassing multiple claims, and which have between three years two months and seven years three 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 the fact that 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. 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 revolutions in surgery. Throughout the history of electrosurgery, companies that have developed significant technological breakthroughs in patient safety have seen their technologies become widely used. As with Isolated electrosurgical generators in the 1970s and with REM technology in the 1980s, AEM technology is receiving the broad endorsements that drove these previous new technologies to becoming a standard of care. Our proprietary AEM technology enhances patient safety in MIS, and clinicians are now widely advocating its use. The expansion of a fully integrated AEM product line, combined with broad independent endorsements, has created momentum for us in the marketplace.

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 fiscal year 2008. Our supplier agreements with Novation and Premier, the two largest Group Purchasing Organizations (GPOs) for hospitals in the U.S., are beginning to expose more hospitals to the benefits of our AEM technology.

Sole Possession of Key Technology Provides Marketing Leverage

We believe that our sole possession of patented AEM technology provides us with marketing leverage toward gaining an increased share of the large market for surgical instruments in MIS.

Market Overview

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 micro-camera and in the variety of available instruments, laparoscopic surgery became popular among general and gynecologic surgeons. Laparoscopy now accounts for a large percentage of all surgical procedures performed in the United States. Approximately 85% of surgeons employ monopolar electrosurgery for laparoscopy (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 Laparoscopic Instruments. Our proprietary AEM product line supplants the conventional non-shielded, non-monitored electrosurgical instruments commonly used in laparoscopic surgery.

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 represents over 90% of our sales in the fiscal year ended March 31, 2008, and we expect this sales stream to grow as the number of newly changed hospitals increases. AEM Instruments are competitively priced 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 GPOs to assist in promoting the benefits of AEM technology. GPOs have significant influence on the market for surgical instruments. Supplier agreements with Novation and Premier is helping to expose AEM technology to new hospitals. Together, Novation and Premier represent over 3,000 hospitals which perform approximately 50% of all surgery in the United States.

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 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 electrosurgical 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 electrosurgical 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. Reports indicate that this situation has even resulted in fatalities.

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 natural course of normal use during surgery. 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. 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 injury 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.

Encision’s AEM Laparoscopic Instruments

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

AEM Laparoscopic 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 Laparoscopic 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 Laparoscopic Instruments provide enhanced patient safety, require no change in surgeon technique and are cost competitive. Thus, conversion to AEM Laparoscopic Instruments can be easy and economical.

Technology Precedents

We believe that gaining broad independent endorsements in the surgical community is a demonstrated and successful method for new surgical technology to advance in the marketplace. From a concern or problem in surgery, the medical device industry develops a technological solution, and this solution evolves to garner credibility and endorsements. Once this occurs, the technology is then widely employed by hospitals to benefit patients, surgeons and the operating room staff. We believe that AEM technology is following the same path as previous revolutions in electrosurgery. As with other safety advances (i.e. Isolated electrosurgical generators in the 1970s and REM technology in the 1980s), AEM technology has received the breadth of independent endorsements that drove previous new technology to broad market acceptance. (REM is a registered trademark of Covidien Ltd. AEM is a registered trademark of Encision Inc.).

Time Period	Problem	Solution	Results
1970s	All electrosurgical units had a grounded design Alternate paths for the current were possible, causing patient burns	Isolated Electrosurgery	Patient safety is improved; New standard of care
1980s	All electrosurgical patient return electrodes were not monitored Patient burns at return electrode site were possible	REM - Return Electrode Monitoring	Patient safety is improved; New standard of care

1990s & 2000s	Introduction of Minimally Invasive Surgery (MIS)	MIS instruments are susceptible to causing stray electrosurgical burns to unintended, unseen tissue	AEM Laparoscopic Instruments Shielded and monitored instruments and the active electrode monitoring system.	Patient safety is improved; Emerging standard of care
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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. Patents were issued to us by the United States Patent and Trademark Office in 1994, 1997, 1998 and 2002.

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. 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 market gains for the technology.

Products

We produce and market a full line of AEM Surgical 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. Our new line of disposable hand-switching fixed tip electrodes offers disposable and reusable alternatives for each of our major product groups. We also have a new line of handles that are used for advanced laparoscopic procedures that incorporate stiffer shafts and ergonomic features. In addition, we market the AEM Monitor product line that is used in conjunction with the AEM Instruments.

Sales and Marketing Overview

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We believe that AEM technology will become the standard of care in laparoscopic surgery worldwide. Our marketing efforts are focused toward capitalizing on substantial independent endorsements for the 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*.

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. Together, this network provides market presence 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 and hospital staff have to be in substantial agreement as to the benefits of new technology), and the consequent 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 marketing efforts are focused toward capitalizing on the substantial independent endorsements which advocate utilizing AEM technology for advancing patient safety in laparoscopic surgery. In addition, there is increasing public interest in the reduction of medical errors and the advancement of patient safety. This interest and focus is reflected in the JCAHO (Joint Commission on Accreditation of Healthcare Organizations) Standards enacted in July 2001 requiring hospitals to show proactive initiatives for advancing patient safety in order to renew their accreditation. Some recent new hospital accounts changing to AEM technology have been motivated in part by these JCAHO patient safety standards. 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 have developed and continue to enhance a network of independent distributors and sales representatives across the U.S. The 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 GPOs. GPOs have significant influence on the market for surgical devices and instruments. We have GPO agreements with Novation and Premier, which together represent over 3,000 hospitals in the United States. We have negotiated a one year extension with Novation through January 31, 2009 and a new three year agreement with Premier effective as of June 1, 2008. While these agreements do not involve purchase commitments, these relationships with Novation and Premier expand the market visibility of AEM technology and smooth the procurement and conversion process for new hospital customers. In fiscal year 2008, approximately thirty percent of our new hospital account sales were sales to members of Novation and Premier.

In addition to the efforts to broaden market acceptance in the United States, we have contracted with independent distributors in Canada, Australia and elsewhere to market our products internationally. We have achieved CE marking for our products so that we may sell into the European marketplace. The CE marking, Conformance Europeene (CE), 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 is 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 the AEM instrument product line to satisfy the evolving needs of surgeons. For AEM technology to fully become a standard of care, we must satisfy surgeons' preferred instrument shapes, sizes, styles and functionality with integrated AEM instruments. This commitment includes expanding the styles of electro-surgical instruments available for MIS applications so that the conversion to AEM technology is transparent to surgeons and does not require significant change in their current surgical techniques. 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 the AEM Laparoscopic Instrument product offering to increase surgeons' choices and options in laparoscopic surgery. Our research and development expenses were \$1,267,834 in fiscal year 2008 and \$1,099,619 in fiscal year 2007. 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 manufacturing and assembly of the AEM Laparoscopic 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 Alinabal, Inc. who accounted for approximately 17% of our purchases in fiscal year 2008, 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 subassemblies 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.

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 28,696 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 August 2007.

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 February 2008.

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 eight relevant patents that together form a significant intellectual property position. We were issued a United States patent having 42 claims on May 17, 1994. This patent relates to the basic shielding and monitoring technologies that we incorporate into our AEM products. Three additional United States patents were issued to us in 1997, 1998 and 2002, 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. There are between three years two months and seven years three months remaining on our AEM patents.

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 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 U.S. Surgical Corporation (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 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 selling concepts, rather than just a product, which results in a longer sales cycle and generally higher sales costs. Independent endorsements of active electrode monitoring technology have greatly enhanced the credibility of AEM Laparoscopic 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. We utilize a network of independent distributor representatives. 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 (i.e., 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.

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 the AEM laparoscopic 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 August 2007, the FDA conducted a Quality System Regulation 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. We have obtained a Certificate of Export from the United States Department of Health and Human Services that states that we have been found to be ...in substantial compliance with Current Good Manufacturing Practices... based on the most recent inspection. However, a specific foreign country in which we wish to sell our products may not accept or continue to accept the Export Certificate. 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 2008. In addition to licensing, entry into the Canadian market now requires quality system certification to ISO 13485:2003. Our quality system was audited and a certification was issued by LGA-InterCert, of Nuremberg, Germany, in February 2008.

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, 2008, we employed 50 full-time individuals, of which 13 are engaged directly in research, development and regulatory activities, 10 in manufacturing/operations, 22 in marketing and sales and 5 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 2. Properties.

We lease 28,696 square feet of office and manufacturing space under noncancelable lease agreements through August 14, 2009 at 6797 Winchester Circle, Boulder, Colorado. We believe that our existing facilities are adequate for our current operations.

Item 3. Legal Proceedings.

We are not involved in any legal proceeding. We may become involved in litigation in the future in the normal course of business.

Item 4. Submission of Matters to a Vote of Security Holders.

There were no matters submitted to a shareholder vote during the fourth quarter of the fiscal year ended March 31, 2008.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.

Our common stock is quoted on the AMEX under the symbol ECI. The following table lists the high and low sales prices for each period indicated:

Fiscal	2008		2007	
	High	Low	High	Low
First quarter	\$ 4.20	\$ 3.14	\$ 3.80	\$ 2.81
Second quarter	\$ 3.40	\$ 2.40	\$ 2.90	\$ 2.21
Third quarter	\$ 2.75	\$ 1.78	\$ 3.31	\$ 2.26
Fourth quarter	\$ 2.30	\$ 1.78	\$ 4.03	\$ 3.00

We have never paid cash dividends on our common stock and have no present plans to do s