

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENCISION INC

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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, 2019

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.

(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 80301

(Address of principal executive offices) (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	ECIA	OTC Bulletin Board

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 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):

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, the aggregate market value of the shares of common stock held by non-affiliates of the issuer on such date was \$2,421,459. This figure is based on the average bid and asked price of \$0.42 per share of the issuer's common stock on September 28, 2018 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

11,558,355

(Class)

(Outstanding at May 31, 2019)

Documents Incorporated by Reference: Definitive Proxy Statement for the 2019 Annual Shareholders' Meeting to be filed with the Securities and Exchange Commission and incorporated by reference as described in Part III. The 2019 Proxy Statement will be filed within 120 days after the end of the fiscal year ended March 31, 2019.

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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 terminology. 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 electrosurgical 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 electrosurgery devices in these procedures. The product opportunity exists in that monopolar electrosurgery instruments used in laparoscopic procedures provide excellent clinical results, but are also 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, including the risk of death, and creates liability exposure for surgeons and hospitals, and increased and preventable readmissions. Our technology helps to reduce hospital risk and liability.

Our patented AEM technology provides surgeons with the desired tissue effects of cutting and coagulating tissue in laparoscopic procedures, while preventing stray electrosurgical 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 a proprietary shield and electrically connect to an Active Electrode Monitor to dynamically and continuously monitor the flow of electrosurgical current, thereby preventing patient injury from stray monopolar energy. With our “shielded and monitored” instruments, surgeons are able to perform electrosurgical procedures more safely, effectively and economically than is possible using conventional instruments.

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 electrosurgical device manufacturers advocate the use of AEM technology. In May 2018, the Food and Drug Administration issued a Safety Communication that stated that, “In addition to serving as an ignition source, monopolar energy use can directly result in unintended patient burns from capacitive coupling and intra-operative insulation failure.”

Business Highlights

Proprietary, Patented Technology

We have developed and launched patented AEM Surgical Instruments and Monitors that enhance patient safety and patient outcomes in laparoscopic surgical procedures. We have been issued 16 unexpired patents relating to AEM technology from the United States Patent and Trademark Office, each encompassing multiple claims, and which have between four and twenty years 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 electrosurgical energy has been well documented. Such injuries can be especially troubling given that often these injuries are out of the field of view, can go unrecognized at the time of surgery, and can lead to a cascade of adverse events, including death. Our patented AEM technology eliminates the risk of stray electrosurgical burns in MIS while providing surgeons with the tissue effects they desire.

Product Line has been Developed and Launched

Our AEM Surgical Instruments and Monitors 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 a full range of instrument sizes, types and styles favored by surgeons. Additionally, we continued to improve quality and added our AEM EndoShield® 2 Burn Protection System ("EndoShield 2") during our fiscal year ended March 31, 2018. The EndoShield 2 can be used for a number of surgical procedures without reprocessing, reduces the customer's cost per use significantly, and eliminates a significant barrier to adoption. 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 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. 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, knowledgeable 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 improved our sales network which provided new hospital accounts with AEM technology in our fiscal year ended March 31, 2019. Our supplier agreements with Group Purchasing Organizations ("GPOs") and other key hospital systems are beginning to expose more hospitals to the benefits of our AEM technology. During the quarter ended March 31, 2019, our proprietary patient safety technology was recognized by the U.S. Department of Veterans Affairs and provides us with the opportunity to market our instruments and monitors into VA Medical Centers. The VA is the largest medical system in the U.S. providing service to more than nine million veterans across more than 1,200 facilities. Also, during the quarter, we were awarded a prestigious Vizient Innovative Technology Contract for monopolar surgical instruments and monitors. Vizient represents a diverse membership base that includes academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers and represents approximately \$100 billion in annual purchasing volume.

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 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 laparoscopic 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 applicators and other surgical instruments of various designs, which provide a variety of tissue effects. Among the laparoscopic hand instruments, approximately \$500 million in sales annually are derived from 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.

When a hospital decides to use our AEM technology, we make recurring sales to such hospital for replacement instruments. Sales from reusable and disposable AEM products in hospitals represented over 90% of our sales in the fiscal year ended March 31, 2019, 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 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 developing new devices that integrate AEM technology, which we believe will have high surgeon appeal. We are also working to improve the reach of our sales network to key decision makers who purchase or recommend the purchase of laparoscopic instruments and electrosurgical devices. We are also pursuing relationships with selected GPOs, hospital systems and integrated delivery networks to assist in promoting the benefits of AEM technology. We are seeking increasing international opportunities for AEM technology sales. We estimate sales outside the U.S. to be at least as large as that of the U.S. market. We are growing our presence in Australia and New Zealand and are seeking a

new presence in the Middle East and Europe. 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 prevalent resource for surgeons. Since its introduction in the 1930s, electrosurgical technology has continually evolved and is estimated to be used in over 75% of all surgeries.

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, coagulation of bleeding tissues, 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 laparoscopic camera systems limit 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.

The dangers of stray energy are twofold. Not only is there the danger created by the burn injury itself, but there is the compounding danger that the burn will go unnoticed during the surgery and be allowed to manifest post-operatively as fecal peritonitis or other potentially deadly and devastating outcomes. In many cases, the surgeon cannot detect stray electrosurgical burns at the time of the procedure because it is out of their field of visualization. The resulting complication usually presents itself days later in the form of a severe infection or sepsis, which often results in a hospital readmission and a difficult course of remedial surgeries and prolonged hospital recovery for the patient. This situation has even resulted in fatalities.

Stray electrosurgical 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. This insulation can fail during the course of normal use during surgery. One university study found insulation defects in new disposable instruments before they were used or after limited surgical use. It is also possible for instrument insulation to become flawed during the handling, cleaning and sterilization process. This common insulation failure can allow electrical currents to “spark” from the instrument to unintended and unseen tissue with potentially serious consequences for the patient, such as bowel perforations. Four different studies indicate that the insulation failure rate in reusable instruments can be as high as one in five. Capacitive coupling is another way stray electrosurgical 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 or another instrument despite intact insulation. This potential for capacitive coupling is present in all laparoscopic surgeries that utilize monopolar electrosurgery devices and are likely to 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 electrosurgical burns in laparoscopy and are the two events over which the surgical team has traditionally had no control. Although alternative forms to monopolar electrosurgery energy exist, these alternative energies tend to be less effective, take longer to achieve the desired surgical effect and are costlier.

Encision’s AEM Surgical Instruments

AEM technology eliminates the risk of stray electrical energy caused by instrument insulation failure and capacitive coupling, and thus prevents unintended burn injuries to patients.

AEM Surgical Instruments are an innovative solution to stray electrosurgical burns in laparoscopic surgery and are designed with the same look, feel and functionality as conventional instruments. They direct electrosurgical energy where the surgeon desires, while continuously monitoring the current flow to prevent stray electrosurgical 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 electrically connected and referenced back to an AEM Monitor at the electrosurgical generator. In the event of a harmful level of stray electrical energy, the monitor shuts down the power at the source, assuring patient safety. If instrument insulation failure should occur, the AEM system, while continually monitoring the instrument, immediately interrupts monopolar output from the electrosurgical generator and alerts the surgical staff. The AEM system protects against capacitive coupling by providing a neutral return path for “capacitive” electrical energy. Capacitive energy is continually drained away from the instrument and away from the patient through the protective shield built into all AEM instruments and the connected AEM Monitor.

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 electrosurgical generators. AEM Surgical Instruments provide enhanced patient safety, require no change in surgeon technique and are cost competitive. Thus, conversion to AEM Surgical Instruments is easy and economical.

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, 2019, we have 16 unexpired United States patents relating to specific implementations of shielding and monitoring in instruments and continue to add patents as we further develop our proprietary technology and its applications.

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 endo-mechanical 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. We introduced our AEM EndoShield® 2 Burn Protection System during our fiscal year ended March 31, 2018. The EndoShield 2 can be used for a number of surgical procedures without reprocessing, reduces the customer’s cost per use significantly, and eliminates a significant barrier to adoption. Thus, hospitals can make a complete and smooth conversion to our product line, thereby advancing patient safety in MIS. The EndoShield 2 integrates our patented AEM technology into a disposable smart cord and eliminates the need for a separate AEM monitor. It is changing the marketplace for electrosurgical devices and laparoscopic instruments by providing a solution to a well documented hazard unique to laparoscopic surgery.

Sales and Marketing Overview

We believe that AEM technology can become the standard of care in laparoscopic surgery worldwide. Our marketing efforts are focused on building awareness by providing technical education for Health Care Providers on the dangers of stray electrosurgical energy and in providing clinical and economic evidence to substantiate the value of AEM technology to Hospitals, their Staff, and their patients. We also leverage relationships with prominent Hospitals and Surgeons where AEM Technology has increased their level of patient care and improved their overall surgical outcomes.

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 in new CMS Hospital Quality Metrics. The Center for Medicare and Medicaid Services published its Hospital-Acquired Condition Reduction Program, effective October 1, 2014. At that time, the program began to levy as much as a 1% penalty on Medicare reimbursements on hospitals in the lower quadrant of performance for selected quality indicators, including accidental puncture and laceration (“APL”). An example of an APL includes the use of a cautery device (electrosurgery) or scissors to dissect a tissue plane that errantly causes an injury to underlying bowels.

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 patient injury and 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 Australia, New Zealand and the Netherlands to market our products internationally. We have achieved Conformité Européene ("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 developing, and sales in international markets are small.

We believe that the expanding awareness for AEM technology through education 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. For AEM technology to fully become a standard of care, we must satisfy surgeons' preferred instrument shapes, sizes, styles and functionality with integrated AEM technology. This commitment includes expanding the styles of electrosurgical 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 our AEM Instrument product offering to increase surgeons' choices and options in laparoscopic surgery. Our research and development expenses were \$779,493 in fiscal year 2019 and \$842,081 in fiscal year 2018. 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, monitors and accessories. We also have relationships with a number of outside suppliers, including ATL Technology, LLC who accounted for approximately 27% of our purchases in fiscal year 2019, 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.

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 October 2015.

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, TUV Rheinland. The most recent audit was completed in February 2019.

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 16 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, 2019, we have 16 unexpired United States patents relating to specific implementations of shielding and monitoring in instruments. As of March 31, 2019, there are between four and twenty years remaining on our AEM patents. We have five 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 Advanced Surgical Technologies Group (a division of Medtronic plc) 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. What clearly differentiates us from the competition is that while competitive technologies may somewhat reduce the risk of stray energy burns, only AEM Technology completely eliminates it.

We also believe that manufacturers of products based on alternative technology to monopolar electrosurgery are our competitors. These alternative technologies include other "advanced energy" technologies such as bipolar electrosurgery, laser surgery and ultrasonic dissector sealers. Leading manufacturers in these areas include Advanced Surgical Technologies 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 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. Our products are Class II devices.

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 October 2015, 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 has expired and we will seek to renew it. 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, TUV Rheinland. The most recent audit was completed in February 2019.

During our March 31, 2018 quarter, we received a letter from the FDA. The letter contained a questionnaire regarding Stray Energy and how to prevent patient injuries from Stray Energy during laparoscopic procedures. We provided the FDA with extensive information on burns and our program for eliminating them. A Safety Communication was released by the FDA on May 29, 2018. It is on the FDA's website at: <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm608637.htm>. The Safety Communication states that, "In addition to serving as an ignition source, monopolar energy use can directly result in unintended patient burns from capacitive coupling and intra-operative insulation failure. If a monopolar electrosurgical units (ESU) is used: Do not activate when near or in contact with other instruments."

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 \$10 million umbrella policy. We maintain customary property and casualty, workers' compensation, employer liability and other commercial insurance policies.

Employees

As of March 31, 2019, we employed 36 full-time and 2 part-time individuals, of which 7 full-time are engaged directly in research, development and regulatory activities, 15 full-time and 2 part-time in manufacturing/operations, 10 full-time in marketing and sales, and 4 full-time time 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.

Available information

Our internet address is www.encision.com. We are not including the information contained in our website as part of, or incorporating it by reference into, this document. We make available, free of charge, through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC.

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:

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 2020 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 \$22 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 compensation expense related to stock options and, in some years, by operating profits. At March 31, 2019, we had \$273,348 in cash available to fund future operations and, in addition, access to a line of credit for \$1 million. 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 July 31, 2018, we signed a new line of credit agreement with Bank of America Merrill Lynch. The facility provides for up to \$1 million revolving line of credit. The interest rate is a rate per year equal to the LIBOR Daily Floating Rate plus 2.75 percentage points. There is a minimum quarterly EBITDA covenant and a minimum Collateral Coverage ratio of 2. Minimum Collateral Coverage is the ratio of gross accounts receivable plus inventory to the line of credit commitment. As of March 31, 2019, we had no borrowings from the credit facility and had an additional \$1 million available to borrow. For the quarters ended December 31, 2018 and March 31, 2019, we were not in compliance with the minimum quarterly EBITDA covenant. There can be no assurance that we would be successful in obtaining alternative sources of funding to repay this obligation. 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 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. Tariffs will increase our material costs and, if they are fully absorbed by us, then they will negatively affect our gross profit margins.

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 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 16 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 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 May 31, 2019, 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 5,827,879 shares, or 50% 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 \$10,000,000 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, Gregory J. Trudel. 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.

Item 1B. Unresolved Staff Comments

Not required for small reporting companies.

Item 2. Properties

We lease 28,696 square feet of office and manufacturing space under noncancelable lease agreements through July 31, 2024 at 6797 Winchester Circle, Boulder, Colorado. We believe that our existing facilities are adequate for our current operations.

Item 3. Legal Proceedings

None at March 31, 2019.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

During our fiscal years 2019 and 2018, our common stock has been quoted on the Pink tier, operated by the OTC Markets Group, 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 these markets, for the periods indicated. The bid quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Fiscal	2019		2018	
	High	Low	High	Low
First quarter	\$ 0.45	\$ 0.33	\$ 0.51	\$ 0.32
Second quarter	\$ 0.52	\$ 0.34	\$ 0.47	\$ 0.30
Third quarter	\$ 0.42	\$ 0.32	\$ 0.56	\$ 0.36
Fourth quarter	\$ 0.39	\$ 0.33	\$ 0.48	\$ 0.28

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, 2019, 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 our 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 \$21,850,147 at March 31, 2019. 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 in future periods.

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 2020, we will focus on growing 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 if our fiscal year 2020 revenues increase, then our fiscal year 2020 gross profit and gross margin, as a percentage of revenue, 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 2020, we expect to have ten 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 internally.

Research and Development Expenses. Research and development expenses are expected to increase to support expansion to our AEM product line, which will further expand the instrument options for the surgeon. New refinements to AEM product lines are planned for introduction in fiscal year 2020.

Results of Operations

Net Revenue. Our net revenue for the fiscal year ended March 31, 2019 ("FY 19") was \$8,802,456, and for the fiscal year ended March 31, 2018 ("FY 18"), net revenue was \$8,754,279. This represents an increase of \$48,177, or 1%, in FY 19 from FY 18. The increase is attributable to new hospital accounts for AEM technology, which increased the installed base of users of reusable and disposable AEM Surgical Instruments. This was partially offset by business lost from hospitals that stopped or reduced using AEM technology. FY 18 included net revenue of \$492,200 from an order for non-AEM product. FY 19 net revenue increased 7% after non-AEM product revenue is excluded from FY 18 net revenue.

Gross profit. Gross profit in FY 19 was \$4,671,600 which represented a decrease of \$335,423, or 7%, from gross profit in FY 18 of \$5,007,023. Gross profit margin was 53% of net revenue for FY 19 and 57% of net revenue for FY 18. The gross profit margin decrease from FY 18 was due to product mix and higher material costs primarily due to the effect of tariffs.

Sales and marketing expenses. Sales and marketing expenses were \$2,763,065 in FY 19, an increase of \$451,298, or 20%, from \$2,311,767 in FY 18. The increase was the result of increased compensation for additional sales people, commissions, sales samples, advertising and printing.

General and administrative expenses. General and administrative expenses were \$1,315,401 in FY 19, a decrease of \$141,941, or 10% from \$1,457,342 in FY 18. The decrease was the result of decreased compensation, bank fees, regulatory fees and bonus accrual elimination. The net decrease was partially offset by increased legal fees.

Research and development expenses. Research and development expenses were \$779,493 in FY 19, a decrease of \$62,588 or 7%, from \$842,081 in FY 18. The decrease was the result of decreased compensation, inventory usage, outside services, test materials and cost allocations. The net decrease was partially offset by increased test materials.

Net income and loss. Net loss in FY 19 of \$236,096 represented a loss increase of \$571,655 compared to FY 18 net income of \$335,559. The decreased income was the result of decreased gross profit and increased operating expenses, as discussed above.

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 \$24,201,769 from our inception through March 31, 2019. Our operations used \$127,242 and provided \$419,441 of cash in FY 19 and FY 18, respectively, on net revenue of and \$8,802,456 and \$8,754,279 in FY 19 and FY 18, respectively. These amounts of cash provided by operations are not indicative of the expected cash to be generated from or used by operations in the fiscal year ending March 31, 2020 ("FY 20"). As of March 31, 2019, we had \$298,348 in cash, cash equivalents and restricted cash, and had an additional \$1 million available under our credit facility to fund future operations. Working capital was \$1,908,748 at March 31, 2019 compared to \$1,575,681 at March 31, 2018. The increase in working capital was primarily caused by an issuance of common stock for \$350,000. Current liabilities were \$1,001,265 at March 31, 2019, compared to \$1,038,485 at March 31, 2018.

On July 31, 2018, we signed a new line of credit agreement with Bank of America Merrill Lynch. The facility provides for up to \$1 million revolving line of credit. The interest rate is a rate per year equal to the LIBOR Daily Floating Rate plus 2.75 percentage points. There is a minimum quarterly EBITDA covenant and a minimum Collateral Coverage ratio of 2. Minimum Collateral Coverage is the ratio of gross accounts receivable plus inventory to the line of credit commitment. As of March 31, 2019, we had no borrowings from the credit facility and had an additional \$1 million available to borrow. For the quarters ended December 31, 2018 and March 31, 2019, we were not in compliance with the minimum quarterly EBITDA covenant.

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 20. We believe that we enter FY 20 having achieved improvements in the clinical credibility of our technology. Our FY 20 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, cash equivalents and restricted cash for FY 20. 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.

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, 2019, net operating loss carryforwards totaling approximately \$10 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 2020. 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 for our facility at 6797 Winchester Circle, Boulder, Colorado. Rent expense for our facilities for the fiscal years ended March 31, 2019 and 2018 was \$305,735 and \$252,911, respectively.

Contractual Obligations

Effective November 9, 2017, we extended our noncancelable lease agreement through July 31, 2024 for our facilities at 6797 Winchester Circle, Boulder, Colorado. The lease includes base rent abatement for the first two months, or \$55,583, and \$145,000 of leasehold improvements granted by the landlord. At the start of the lease on August 1, 2019, the \$145,000 will be recorded on our condensed balance sheets as leasehold improvements and deferred rent. The leasehold improvements will be amortized over the lesser of the lease term or the assets life and the deferred rent will be amortized against rent expense over the lease term. Lease expense was \$305,735 and \$252,911 for the fiscal years ended March 31, 2019 and 2018, respectively. The minimum future lease payment, by fiscal year, as of March 31, 2019 is as follows:

Fiscal Year	Amount
2020	322,738
2021	343,167
2022	357,667
2023	372,167
2024	386,667
2025	130,500
Total	\$ 1,912,906

On July 31, 2018, we signed a new line of credit agreement with Bank of America Merrill Lynch. The facility provides for up to \$1 million revolving line of credit. The interest rate is a rate per year equal to the LIBOR Daily Floating Rate plus 2.75 percentage points. There is a minimum quarterly EBITDA covenant and a minimum Collateral Coverage ratio of 2. Minimum Collateral Coverage is the ratio of gross accounts receivable plus inventory to the line of credit commitment. As of March 31, 2019, we had no borrowings from the credit facility and had an additional \$1 million available to borrow. For the quarters ended December 31, 2018 and March 31, 2019, we were not in compliance with the minimum quarterly EBITDA covenant.

As of March 31, 2019, the following table shows our contractual obligations for the periods presented:

	Payment due by period				
	Totals	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Lease obligations	\$ 1,912,906	\$ 322,738	\$ 700,834	\$ 758,834	\$ 130,500

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.

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 statements of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

The following financial statements are included in this Report:

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Statements of Operations for the fiscal years ended March 31, 2019 and 2018	19
Statements of Shareholders' Equity for the fiscal years ended March 31, 2019 and 2018	20
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Encision Inc.
Boulder, Colorado

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Encision Inc. as of March 31, 2019 and 2018 and the related statements of operations, shareholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of Encision Inc. as of March 31, 2019 and 2018, 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.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to Encision Inc. in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Encision Inc. is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risk of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Eide Bailly LLP

We have served as the Company's auditor since 2008.

Denver, Colorado
June 14, 2019

Encision Inc.
Balance Sheets

	March 31, 2019	March 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 273,348	\$ 114,538
Restricted cash	25,000	25,000
Accounts receivable, net of allowance for doubtful accounts of \$26,000 at March 31, 2019 and \$20,500 at March 31, 2018	1,009,106	962,639
Inventories, net of reserve for obsolescence of \$50,000 at March 31, 2019 and \$21,000 at March 31, 2018	1,472,543	1,437,159
Prepaid expenses	130,016	74,830
Total current assets	<u>2,910,013</u>	<u>2,614,166</u>
Equipment:		
Furniture, fixtures and equipment, at cost	3,061,329	3,021,968
Accumulated depreciation	<u>(2,811,761)</u>	<u>(2,673,037)</u>
Equipment, net	249,568	348,931
Patents, net of accumulated amortization of \$266,028 at March 31, 2019 and \$238,571 at March 31, 2018	248,579	270,504
Other assets	19,548	18,873
TOTAL ASSETS	<u>\$ 3,427,708</u>	<u>\$ 3,252,474</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 578,956	\$ 466,418
Accrued compensation	295,875	257,133
Other accrued liabilities	126,434	284,550
Deferred rent	—	30,384
Total current liabilities	<u>1,001,265</u>	<u>1,038,485</u>
Long-term liability:		
Deferred rent	74,821	10,128
Total liabilities	<u>1,076,086</u>	<u>1,048,613</u>
Commitments and contingencies (Note 4)		
Shareholders' equity:		
Preferred stock, no par value: 10,000,000 shares authorized; none issued and outstanding	—	—
Common stock and additional paid-in capital, no par value: 100,000,000 shares authorized; 11,558,355 and 10,683,355 issued and outstanding at March 31, 2019 and 2018, respectively	24,201,769	23,817,912
Accumulated (deficit)	<u>(21,850,147)</u>	<u>(21,614,051)</u>
Total shareholders' equity	<u>2,351,622</u>	<u>2,203,861</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 3,427,708</u>	<u>\$ 3,252,474</u>

The accompanying notes to financial statements are an integral part of these statements.

Encision Inc.
Statements of Operations

Years Ended	March 31, 2019	March 31, 2018
NET REVENUE	\$ 8,802,456	\$ 8,754,279
COST OF REVENUE	4,130,856	3,747,256
GROSS PROFIT	4,671,600	5,007,023
OPERATING EXPENSES:		
Sales and marketing	2,763,065	2,311,767
General and administrative	1,315,401	1,457,342
Research and development	779,493	842,081
Total operating expenses	4,857,959	4,611,190
OPERATING INCOME (LOSS)	(186,359)	395,833
Interest expense, net	(50,334)	(60,643)
Other income, net	597	369
Interest and other income, net	(49,737)	(60,274)
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	(236,096)	335,559
Provision for income taxes	—	—
NET INCOME (LOSS)	\$ (236,096)	\$ 335,559
Net income (loss) per share—basic and diluted	\$ (0.02)	\$ 0.03
Weighted average shares—basic	10,932,670	10,683,355
Weighted average shares—diluted	10,932,670	10,707,126

The accompanying notes to financial statements are an integral part of these statements.

Encision Inc.
Statements of Shareholders' Equity

	<u>Shares of Common Stock</u>	<u>Common Stock and Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>
BALANCES AT MARCH 31, 2017	10,683,355	\$ 23,752,131	\$ (21,949,610)	\$ 1,802,521
Net income	—	—	335,559	335,559
Compensation expense related to equities	—	65,781	—	65,781
BALANCES AT MARCH 31, 2018	10,683,355	23,817,912	(21,614,051)	2,203,861
Net loss	—	—	(236,096)	(236,096)
Compensation expense related to equities	—	37,027	—	37,027
Common stock issued	875,000	346,830	—	346,830
BALANCES AT MARCH 31, 2019	<u>11,558,355</u>	<u>\$ 24,201,769</u>	<u>\$ (21,850,147)</u>	<u>\$ 2,351,622</u>

The accompanying notes to financial statements are an integral part of these statements.

Encision Inc.
Statements of Cash Flows

Years Ended	March 31, 2019	March 31, 2018
Cash flows from (used in) operating activities:		
Net income (loss)	\$ (236,096)	\$ 335,559
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	182,066	202,895
Stock-based compensation expense related to stock options	37,027	65,781
(Recovery from) provision for doubtful accounts, net change	5,500	(12,500)
(Recovery from) provision for inventory obsolescence, net change	29,000	(29,000)
Change in operating assets and liabilities:		
Accounts receivable	(51,967)	92,142
Inventories	(64,384)	(279,747)
Prepaid expenses and other assets	(55,861)	(14,963)
Accounts payable	112,538	63,504
Accrued compensation and other accrued liabilities	(85,065)	(4,230)
Net cash provided by (used in) operating activities	<u>(127,242)</u>	<u>419,441</u>
Cash flows (used in) investing activities:		
Acquisition of property and equipment	(55,246)	(56,562)
Patent costs	(5,532)	(43,403)
Net cash (used in) investing activities	<u>(60,778)</u>	<u>(99,965)</u>
Cash flows from (used in) financing activities:		
Paydowns to credit facility, net change	—	(275,055)
Change in restricted cash	—	25,000
Proceeds from the issuance of common stock	350,000	—
Cost of the issuance of common stock	(3,170)	—
Net cash provided by (used in) financing activities	<u>346,830</u>	<u>(250,055)</u>
Net increase in cash, cash equivalents and restricted cash	158,810	69,421
Cash, cash equivalents and restricted cash, beginning of fiscal year	139,538	70,117
Cash, cash equivalents and restricted cash, end of fiscal year	<u>\$ 298,348</u>	<u>\$ 139,538</u>
Supplemental disclosures of cash flow information:		
Cash paid during the year for interest	\$ 42,914	\$ 50,643

The accompanying notes to financial statements are an integral part of these statements.

NOTES TO FINANCIAL STATEMENTS**1. Description of Business and Basis of Presentation**

Encision Inc. is a medical device company that designs, develops, manufactures and markets patented surgical instruments that provide greater safety to patients undergoing minimally-invasive surgery. We believe that our patented AEM[®] surgical instrument technology is changing the marketplace for electrosurgical devices and instruments by providing a solution to a well-documented risk in laparoscopic surgery. Our sales to date have been made primarily in the United States.

We have an accumulated deficit of \$21,850,147 at March 31, 2019. 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 by operating profits. Our liquidity has diminished because of prior years' operating losses, and we may be required to seek additional capital in the future.

Our strategic marketing and sales plan is designed to expand the use of our products in surgically active hospitals in the United States.

We had a net (loss) income available to shareholders of \$(236,096) and 335,559 for the fiscal years ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had cash and cash equivalents of \$273,348, working capital of \$1,908,748 and a line of credit of \$1 million. During the fiscal year ended March 31, 2019, the Company used cash in operations of \$127,242. The principal difference between the net loss of \$236,096 and cash used in operations was the non-cash expenses of depreciation, amortization and stock-based compensation expense related to stock options, for a total of \$219,093. The principal reason for our loss for the fiscal year ended March 31, 2019 was higher material costs as a result of the governmental tariffs. These facts and circumstances were initial indicators that created uncertainty about our ability to continue as a going concern. To address this uncertainty, management has developed plans to ensure that we have the working capital necessary to fund operations. We had continued revenue growth of seven percent from our AEM product revenue. Management concludes that it is probable that our cash resources and our \$1 million line of credit will be sufficient to meet our cash requirements for twelve months from the issuance of the consolidated financial statements. In the event that the governmental tariffs are reduced or eliminated then we expect that the higher material costs that we experienced will be reduced. We are increasing our pricing on products to mitigate somewhat our higher material costs. Therefore, the accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern.

2. Summary of Significant Accounting Policies

Use of Estimates in the Preparation of Financial Statements. The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions. Such estimates and assumptions affect the reported amounts of assets and liabilities as well as disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expense during the reporting period. Actual results could differ from those estimates.

Cash, Cash Equivalents and Restricted Cash For purposes of reporting cash flows, we consider all cash and highly liquid investments with an original maturity of three months or less to be cash equivalents. Restricted cash is cash that was deposited to obtain a letter of credit for our importing and exporting activities.

Fair Value of Financial Instruments. Our financial instruments consist of cash, cash equivalents and restricted cash and short-term trade receivables, payables and line of credit. The carrying values of cash, cash equivalents and restricted cash, short-term receivables, payables and line of credit approximate their fair value due to their short maturities.

Concentration of Credit Risk. Financial instruments, which potentially subject us to concentrations of credit risk, consist of cash and cash equivalents, accounts receivable and accounts payable. The carrying value of all financial instruments approximates fair value. The amount of cash on deposit with financial institutions occasionally exceeds the \$250,000 federally insured limit at March 31, 2019. However, we believe that cash on deposit that exceeds \$250,000 in the financial institutions is financially sound and the risk of loss is minimal.

We have no significant off-balance sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. We maintain the majority of our cash balances with one financial institution in the form of demand deposits.

Accounts receivable are typically unsecured and are derived from transactions with and from entities in the healthcare industry primarily located in the United States. Accordingly, we may be exposed to credit risk generally associated with the healthcare industry. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We charge interest on past due accounts on a case-by-case basis.

A summary of the activity in our allowance for doubtful accounts is as follows:

Years Ended	March 31, 2019	March 31, 2018
Balance, beginning of year	\$ 20,500	\$ 33,000
Provision for (recoveries of) estimated losses	(560)	(10,982)
Write-off of uncollectible accounts	6,060	(1,518)
Balance, end of year	\$ 26,000	\$ 20,500

The net accounts receivable balance at March 31, 2019 of \$1,009,106 included no more than 8% from any one customer. The net accounts receivable balance at March 31, 2018 of \$962,639 included no more than 7% from any one customer.

Warranty Accrual. 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, our warranty obligation is based upon historical experience and is also affected by product failure rates and material usage incurred in correcting a product failure. Should actual product failure rates or material usage costs differ from our estimates, revisions to the estimated warranty liability would be required. A summary of our warranty claims activity, included in other accrued liabilities, is as follows:

Years Ended	March 31, 2019	March 31, 2018
Balance, beginning of year	\$ 10,000	\$ 20,000
Provision for estimated warranty claims	4,592	(10,741)
Claims made	(4,592)	(741)
Balance, end of year	\$ 10,000	\$ 10,000

Inventories. Inventories are stated at the lower of cost (first-in, first-out basis) or net realizable value. We reduce inventory for estimated obsolete or unmarketable inventory equal to the difference between the cost of inventory and the net realizable 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.

At March 31, 2019 and 2018, inventory consisted of the following:

	March 31, 2019	March 31, 2018
Raw materials	\$ 1,063,780	\$ 941,964
Finished goods	458,763	516,195
Total gross inventories	1,522,543	1,458,159
Less reserve for obsolescence	(50,000)	(21,000)
Total net inventories	\$ 1,472,543	\$ 1,437,159

A summary of the activity in our inventory reserve for obsolescence is as follows:

Years Ended	March 31, 2019	March 31, 2018
Balance, beginning of year	\$ 21,000	\$ 50,000
Provision for estimated obsolescence	29,000	3,816
Write-off of obsolete inventory	—	(32,816)
Balance, end of year	\$ 50,000	\$ 21,000

Property and Equipment. 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. Depreciation expense for the years ended March 31, 2019 and 2018 was \$154,609 and \$176,016, respectively.

Long-Lived Assets. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. A long-lived asset is considered impaired when estimated future cash flows related to the asset, undiscounted and without interest, are insufficient to recover the carrying amount of the asset. If deemed impaired, the long-lived asset is reduced to its estimated fair value. Long-lived assets to be disposed of are reported at the lower of their carrying amount or estimated fair value less cost to sell.

Patents. The costs of applying for patents are capitalized and amortized on a straight-line basis over the lesser of the patent's economic or legal life (20 years from the date of application in the United States). Capitalized costs are expensed if patents are not issued. We review the carrying value of our patents periodically to determine whether the patents have continuing value and such reviews could result in the conclusion that the recorded amounts have been impaired. A summary of our patents at March 31, 2019 and 2018 is as follows:

	March 31, 2019	March 31, 2018
Patents issued	\$ 447,430	\$ 447,430
Accumulated amortization	(254,992)	(233,390)
Patents issued, net of accumulated amortization	<u>192,438</u>	<u>214,040</u>
Patent applications	67,176	61,645
Accumulated amortization	(11,035)	(5,181)
Patent applications, net of accumulated amortization	<u>56,141</u>	<u>56,464</u>
Total net patents and patent applications	<u>\$ 248,579</u>	<u>\$ 270,504</u>

The expected annual amortization expense related to patents and patent applications as of March 31, 2019, for the next five fiscal years, is as follows:

Fiscal Year	Amount
2020	\$ 27,456
2021	24,599
2022	23,876
2023	20,958
2024 and following	<u>151,690</u>
Total	<u>\$ 248,579</u>

Other Accrued Liabilities. At March 31, 2019 and 2018, other accrued liabilities consisted of the following:

	March 31, 2019	March 31, 2018
Bonus	\$ —	\$ 108,000
Warranty	10,000	10,000
Sales commissions	50,129	45,068
Lease normalization	—	23,939
Sales and use tax	22,494	17,434
Marketing fees	4,041	7,278
Professional fees	—	37,500
Payroll taxes	27,188	24,114
Miscellaneous	12,582	11,217
Total other accrued liabilities	<u>\$ 126,434</u>	<u>\$ 284,550</u>

Income Taxes. We account for income taxes under the provisions of ASC Topic 740, "Accounting for Income Taxes" ("ASC 740"). ASC 740 requires recognition of 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. ASC 740 also requires recognition of deferred tax assets for the expected future tax effects of all deductible temporary differences, loss carryforwards and tax credit carryforwards. 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 some or all of the valuation allowance should be reversed (Note 5).

ASC 740 prescribes a comprehensive model for how companies should recognize, measure, present, and disclose in their financial statements uncertain tax positions taken or expected to be taken on a tax return. Under ASC 740, tax positions must initially be recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts.

The cumulative effect of adopting ASC 740 on April 1, 2007 has been recorded net in deferred tax assets, which resulted in no ASC 740 liability on the balance sheet. The total amount of unrecognized tax benefits as of the date of adoption was zero. There are open statutes of limitations for taxing authorities in federal and state jurisdictions to audit the Company's tax returns from fiscal year ended March 31, 1999 through the current period. Our policy is to account for income tax related interest and penalties in income tax expense in the statements of operations. There have been no income tax related interest or penalties assessed or recorded. Because the Company has provided a full valuation allowance on all of its deferred tax assets, the adoption of ASC 740 had no impact on our effective tax rate.

Revenue Recognition. Revenue from product sales, net of discounts, are recorded when we ship the product and title has passed to the customer, provided that we have evidence of a customer arrangement and can conclude that collection is probable. Our shipping policy is FOB Shipping Point. We recognize revenue from sales to stocking distributors when there is no right of return, other than for normal warranty claims. We have no ongoing obligations related to product sales, except for normal warranty.

Sales Taxes. We collect sales tax from customers and remit the entire amount to each respective state. We recognize revenue from product sales net of sale taxes.

Research and Development Expenses. We expense research and development costs for products and processes as incurred.

Advertising Costs. We expense advertising costs as incurred. Advertising expense for the years ended March 31, 2019 and 2018 was minimal.

Stock-Based Compensation. Stock-based compensation is presented in accordance with the guidance of 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 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 statements of operations.

ASC 718 requires companies to estimate the fair value of share-based payment awards 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 the accompanying statements of operations.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in our statements of operations for fiscal years 2019 and 2018 included compensation expense for share-based payment awards granted prior to, but not yet vested as of March 31, 2019, based on the grant date fair value. Compensation expense for all share-based payment is recognized using the straight-line, single-option method. As stock-based compensation expense recognized in the accompanying statements of operations for fiscal years 2019 and 2018 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We used the Black-Scholes option-pricing model ("Black-Scholes model") to determine fair value. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. Although the fair value of employee stock options is determined in accordance with ASC 718 using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Stock-based compensation expense recognized under ASC 718 for fiscal years 2019 and 2018 was \$37,027 and \$65,781, respectively, which consisted of stock-based compensation expense related to director and employee stock options.

Stock-based compensation expense related to director and employee stock options under ASC 718 for fiscal years 2019 and 2018 was allocated as follows:

Years Ended	March 31, 2019	March 31, 2018
Cost of sales	\$ 2,026	\$ 2,157
Sales and marketing	4,034	13,679
General and administrative	28,919	45,513
Research and development	2,048	4,432
Stock-based compensation expense	<u>\$ 37,027</u>	<u>\$ 65,781</u>

Segment Reporting. We have concluded that we have one operating segment.

Basic and Diluted Income per Common Share. Net income per share is calculated in accordance with ASC Topic 260, "Earnings Per Share" ("ASC 260"). Under the provisions of ASC 260, basic net income per common share is computed by dividing net income for the period by the weighted average number of common shares outstanding for the period. Diluted net income per common share is computed by dividing the net income for the period by the weighted average number of common and potential common shares outstanding during the period if the effect of the potential common shares is dilutive. Because we had a loss in fiscal years 2019 and 2018, the shares used in the calculation of dilutive potential common shares exclude options to purchase shares and RSUs. Therefore, basic net loss per common share equals dilutive net loss per common share:

The following table presents the calculation of basic and diluted net income (loss) per share:

Years Ended	March 31, 2019	March 31, 2018
Net income (loss)	\$ (236,096)	\$ 335,559
Weighted-average shares — basic	10,932,670	10,683,355
Effect of dilutive potential common shares	—	23,771
Weighted-average shares — basic and diluted	10,932,670	10,707,126
Net loss per share — basic and diluted	<u>\$ (0.02)</u>	<u>\$ 0.03</u>
Antidilutive equity units	990,286	983,765

Recent Accounting Pronouncements. We have reviewed all recently issued, but not yet effective, accounting pronouncements.

ASU No. 2014-09 (ASC 606), Revenue from Contracts with Customers became effective for us beginning April 1, 2018, and adopted the new accounting standard using the modified retrospective transition approach. We record revenue under ASC 606 at a single point in time, when control is transferred to the customer, which is consistent with past practice. We will continue to apply our current business processes, policies, systems and controls to support recognition and disclosure under the new standard. Based on the results of the evaluation, we have determined that the adoption of the new standard presents no material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which modified lease accounting for both lessees and lessors to increase transparency and comparability by recognizing lease assets and lease liabilities by lessees for those leases classified as operating leases under previous accounting standards and disclosing key information about leasing arrangements. Within the opening balances for the fiscal year beginning April 1, 2019, we will recognize leased assets and corresponding liabilities in other long-term assets of \$1,280,000.

3. Shareholders' Equity

Stock Option Plans. We have a stock option plan, the 2007 Stock Option Plan, and we adopted our 2014 Equity Incentive Plan (the "Plan," as summarized below) to promote our and our shareholders' interests by helping us to attract, retain and motivate our key employees and associates. Under the terms of the Plan, the Board of Directors may grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, and other stock-based awards. The purchase price of the shares subject to a stock option will be the fair market value of our common stock on the date the stock option is granted. Generally, vesting of stock options occurs such that 20% becomes exercisable on each anniversary of the date of grant for each of the five years following the grant date of such option. Generally, all stock options must be exercised within five years from the date granted. The number of common shares reserved for issuance under the Plan is 700,000 shares of common stock, subject to adjustment for dividend, stock split or other relevant changes in our capitalization.

Under ASC 718, the value of each employee stock option was estimated on the date of grant using the Black-Scholes model for the purpose of financial information in accordance with ASC 718. The use of a Black-Scholes model requires the use of actual employee exercise behavior data and the use of a number of assumptions including expected volatility, risk-free interest rate and expected dividends. Employee stock options for 437,000 and 200,000 shares of stock were granted during fiscal years 2019 and 2018, respectively.

As of March 31, 2019, \$186,000 of total unrecognized compensation costs related to nonvested stock is expected to be recognized over a period of five years. The assumptions for employee stock options are summarized as follows:

Years Ended	March 31, 2019	March 31, 2018
Risk-free interest rate	2.2% to 3.1%	1.8% to 1.9%
Expected life (in years)	5.0	5.0
Expected volatility	87% to 91%	93% to 95%
Expected dividend	0%	0%

Cumulative compensation cost recognized in net income or loss with respect to options that are forfeited prior to vesting is adjusted as a reduction of compensation expense in the period of forfeiture. The volatility of the stock is based on the historical volatility for the period that approximates the expected lives of the options being valued. Fair value computations are highly sensitive to the volatility factor; the greater the volatility, the higher the computed fair value of options granted.

The total fair value of options granted was computed to be approximately \$107,000 and \$65,000, for the fiscal years ended March 31, 2019 and 2018, respectively. For disclosure purposes, these amounts are amortized ratably over the vesting periods of the options. Effects of stock-based compensation, net of the effect of forfeitures, totaled \$37,027 and \$65,781 for fiscal years 2019 and 2018, respectively.

The Black-Scholes model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the use of assumptions, including the expected stock price volatility. Because our employee stock options have characteristics significantly different than those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock options. A summary of our stock option activity and related information for equity compensation plans approved by security holders for each of the fiscal years ended March 31, 2019 and 2018 is as follows:

	STOCK OPTIONS OUTSTANDING	
	Number Outstanding	Weighted-Average Exercise Price per Share
BALANCE AT MARCH 31, 2017	685,000	\$ 0.63
Granted	200,000	0.45
Forfeited/expired	(126,750)	0.75
BALANCE AT MARCH 31, 2018	758,250	\$ 0.56
Granted	152,000	0.36
Forfeited/expired	(238,250)	0.79
BALANCE AT MARCH 31, 2019	672,000	\$ 0.43

A summary of our stock option activity and related information for equity compensation plans not approved by security holders for the fiscal year ended March 31, 2019 is as follows:

	STOCK OPTIONS OUTSTANDING	
	Number Outstanding	Weighted-Average Exercise Price per Share
BALANCE AT MARCH 31, 2017	245,000	\$ 0.96
Granted	—	—
Forfeited/expired	(20,000)	—
BALANCE AT MARCH 31, 2018	225,000	1.00
Granted	285,000	0.35
Forfeited/expired	(216,000)	0.83
BALANCE AT MARCH 31, 2019	294,000	\$ 0.49

The following table summarizes information about employee stock options outstanding and exercisable at March 31, 2019:

Range of Exercise Prices	STOCK OPTIONS OUTSTANDING			STOCK OPTIONS EXERCISABLE		
	Number Outstanding	Weighted-Average Remaining Contractual Life (in Years)	Weighted-Average Exercise Price per Share	Number Exercisable	Weighted-Average Exercise Price per Share	
\$0.30 - \$0.35	505,000	3.9	\$ 0.33	126,564	\$ 0.31	
\$0.38 - \$0.50	359,000	3.5	\$ 0.43	109,223	\$ 0.47	
\$0.70 - \$1.15	102,000	0.4	\$ 0.59	96,355	\$ 0.93	
	<u>966,000</u>	3.4	\$ 0.39	<u>332,142</u>	\$ 0.54	

A summary of our RSU activity and related information for equity compensation plans approved by security holders for the fiscal year ended March 31, 2019 is as follows:

	RSUs OUTSTANDING	
	Number Outstanding	Weighted-Average Exercise Price per Share
BALANCE AT MARCH 31, 2018	24,286	\$ 0.62
Granted	—	—
Forfeited/expired	—	—
BALANCE AT MARCH 31, 2019	24,286	\$ 0.62

The 966,000 options outstanding as of March 31, 2019 are nonqualified stock options. The exercise price of all options granted through March 31, 2019 has been equal to or greater than the fair market value, as determined by our Board of Directors or based upon publicly quoted market values of our common stock on the date of the grant. As of March 31, 2019, 24,286 equity units for our common stock remain available for grant under the Plan.

4. Commitments and Contingencies

Effective November 9, 2017, we extended our noncancelable lease agreement through July 31, 2024 for our facilities at 6797 Winchester Circle, Boulder, Colorado. The lease includes base rent abatement for the first two months, or \$55,583, and \$145,000 of leasehold improvements granted by the landlord. At the start of the lease on August 1, 2019, the \$145,000 will be recorded on our condensed balance sheets as leasehold improvements and deferred rent. The leasehold improvements will be amortized over the lesser of the lease term or the assets life and the deferred rent will be amortized against rent expense over the lease term. Lease expense was \$305,735 and \$252,911 for the fiscal years ended March 31, 2019 and 2018, respectively. The minimum future lease payment, by fiscal year, as of March 31, 2019 is as follows:

Fiscal Year	Amount
2020	322,738
2021	343,167
2022	357,667
2023	372,167
2024	386,667
2025	130,500
Total	\$ 1,912,906

On July 31, 2018, we signed a new line of credit agreement with Bank of America Merrill Lynch. The facility provides for up to \$1 million revolving line of credit and is secured by accounts receivable and inventory. The interest rate is a rate per year equal to the LIBOR Daily Floating Rate plus 2.75 percentage points. There is a minimum quarterly EBITDA covenant and a minimum Collateral Coverage ratio of 2. Minimum Collateral Coverage is the ratio of gross accounts receivable plus inventory to the line of credit commitment. As of March 31, 2019, we had no borrowings from the credit facility and had an additional \$1 million available to borrow. For the quarters ended December 31, 2018 and March 31, 2019, we were not in compliance with the minimum quarterly EBITDA covenant.

We are subject to regulation by the United States Food and Drug Administration ("FDA"). The FDA provides regulations governing the manufacture and sale of our products and regularly inspects us and other manufacturers to determine our and their compliance with these regulations. As of March 31, 2019, we believe we were in substantial compliance with all known regulations. FDA inspections are conducted periodically at the discretion of the FDA. We were last inspected in December 2012 and were notified of five observations from that inspection, none of which we believe to be material.

Our obligation with respect to employee severance benefits is minimized by the "at will" nature of the employee relationships. Our total obligation with respect to contingent severance benefit obligations was none as of March 31, 2019 and 2018.

5. Income Taxes

We account for income taxes under ASC 740, which requires the use of the liability method. ASC 740 provides that deferred income tax assets and liabilities are recorded based on the differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes, referred to as temporary differences. Deferred income tax assets and liabilities at the end of each period are determined using the currently enacted tax rates applied to taxable income in the periods in which the deferred income tax assets and liabilities are expected to be settled or realized.

The following is a reconciliation between the effective rate and the federal statutory rate used in determining deferred tax assets:

Years Ended	March 31, 2019	March 31, 2018
Expected income tax rate	\$ (50,000)	\$ 103,000
State income taxes, net of federal tax benefit	(8,000)	12,000
Change in valuation allowance	92,000	(1,650,000)
Other permanent differences	20,000	27,000
Research credits	(54,000)	—
Rate change	—	1,491,000
Other differences	—	17,000
Income tax expense	<u>\$ —</u>	<u>\$ —</u>

The components of the net accumulated deferred income tax asset (liability) are as follows:

Years Ended	March 31, 2019	March 31, 2018
Other deferred assets	\$ 64,000	\$ 45,000
Valuation allowance	(64,000)	(45,000)
Current deferred tax assets	—	—
Credits and net operating loss carryforwards	2,742,000	3,003,000
Valuation allowance	(2,742,000)	(3,003,000)
Long-term deferred tax assets	—	—
Total deferred tax assets	—	—
Valuation allowance	—	—
Long-term deferred tax liabilities	—	—
Total deferred tax liabilities	—	—
Net deferred tax assets (liabilities)	\$ —	\$ —

The primary components of our deferred tax assets are described below:

Years Ended	March 31, 2019	March 31, 2018
Differences in reporting long-term assets	\$ 64,000	\$ 45,000
Credits and net operating loss carryforwards	2,742,000	3,003,000
Less valuation allowance	(2,806,000)	(3,048,000)
Total deferred tax assets	\$ —	\$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which net operating losses and reversal of timing differences may offset taxable income. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

As of March 31, 2019, we had approximately \$10 million of net operating loss carryovers for tax purposes. Additionally, we have approximately \$292,000 of research and development tax credits available to offset future federal income taxes. The net operating loss and credit carryovers begin to expire in the fiscal year ended March 31, 2020. In the fiscal year ended March 31, 2020, net operating loss of approximately \$1,1 million will expire if sufficient taxable income is not available to use it. In fiscal years ended after March 31, 2019, net operating losses expire at various dates through March 31, 2039. Our net operating loss carryovers at March 31, 2019 include \$455,000 in income tax deductions related to stock options which will be tax effected and the benefit will be reflected as a credit to additional paid-in capital when realized. As such, these deductions are not reflected in our deferred tax assets. The Internal Revenue Code contains provisions, which may limit the net operating loss carryforwards available to be used in any given year if certain events occur, including significant changes in ownership interests.

6. Major Customers/Suppliers

We depend on sales that are generated from hospitals' ongoing usage of AEM surgical instruments. In fiscal year 2019, we generated sales from over 300 hospitals that have changed to AEM products, but no hospital customer contributed more than 5% to the total sales. We have a relationship with ATL Technology, LLC who accounted for approximately 27%, Aeroswiss, Inc. who accounted for approximately 18%, and Bovie Medical Company who accounted for approximately 11%, respectively, of our purchases in fiscal year 2019.

7. Defined Contribution Employee Benefit Plan

We have adopted a 401(k) Profit Sharing Plan which covers all full-time employees who have completed at least three months of full-time continuous service and are age eighteen or older. Participants may defer up to 20% of their gross pay up to a maximum limit determined by law. Participants are immediately vested in their contributions. We may make discretionary contributions based on corporate financial results for the fiscal year. To date, we have not made contributions to the 401(k) Profit Sharing Plan. Vesting in a contribution account (our contribution) is based on years of service, with a participant fully vested after five years of credited service.

8. Related Party Transaction

We paid consulting fees of \$67,102 and \$73,195 to an entity owned by one of our directors in fiscal years 2019 and 2018, respectively.

9. Subsequent Events

Management evaluated all activity of us and concluded that, as of the date the financial statements were issued, no subsequent events have occurred that would require recognition in the financial statements or disclosure in the notes to the financial statements.

Item 9 Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9 A (T). Controls and Procedures.

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and the Principal Accounting Officer concluded that our disclosure controls and procedures were effective as of March 31, 2019.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013.

Based on its assessment of internal control over financial reporting, management has concluded that, as of March 31, 2019, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

Changes In Internal Control Over Financial Reporting

There were no significant changes in our internal control over financial reporting during the three months ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9 B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information in response to this item is incorporated by reference from the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders to be filed within 120 days after March 31, 2019.

Item 11. Executive Compensation.

Information in response to this item is incorporated by reference from the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders to be filed within 120 days after March 31, 2019.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

Information in response to this item is incorporated by reference from the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders to be filed within 120 days after March 31, 2019.

The following table summarizes certain information regarding our equity compensation plan as of March 31, 2019:

Plan Category	Number of securities to be issued upon exercise of outstanding equity units	Weighted-average exercise price of equity units	Number of securities remaining available for future issuance under equity units plan
Equity compensation plans approved by security holders	696,286	\$ 0.43	3,714
Equity compensation plans not approved by security holders	294,000	\$ 0.49	—
Total	990,286	\$ 0.45	3,714

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information in response to this item is incorporated by reference from the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders to be filed within 120 days after March 31, 2019.

Item 14. Principal Accounting Fees and Services.

Information in response to this item is incorporated by reference from the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders to be filed within 120 days after March 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(b) Exhibits - The following exhibits are attached to this report on Form 10-K or are incorporated herein by reference:

- 3.1 Articles of Incorporation of the Company, as amended. (Incorporated by reference from Registration Statement #333-4118-D dated June 25, 1996).
- 3.2 [Bylaws of the Company. \(Incorporated by reference from Current Report on Form 8-K filed on October 30, 2007\).](#)
- 3.3 [First Amended and Restated Bylaws \(incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 31, 2017\).](#)
- 4.1 Form of certificate for shares of Common Stock. (Incorporated by reference from Registration Statement #333-4118-D dated June 25, 1996).
- 4.2 [Description of Capital Stock**](#)
- 10.1 [Lease Agreement dated June 3, 2004 between Encision Inc. and DaPuzzo Investment Group, LLC \(Incorporated by reference from Quarterly Report on Form 10-QSB filed on August 12, 2004\).](#)
- 10.2 [Encision Inc. 2007 Stock Option Plan \(Incorporated by reference from Proxy Statement dated June 30, 2007\).](#) †
- 10.3 [Encision Inc. 2014 Stock Option Plan \(Incorporated by reference from Proxy Statement dated July 11, 2014\).](#) †
- 10.4 [Employment Agreement, dated December 17, 2013, between Encision Inc. and Gregory J. Trudel \(Incorporated by reference from Current Report on Form 8-K filed on December 23, 2013\).](#) †
- 10.5 [Employment Agreement, dated November 14, 2016, between Encision Inc. and Gregory J. Trudel \(Incorporated by reference to Exhibit 10-1 to our Current Report on Form 8-K filed on November 18, 2016\).](#) †
- 10.6 [Loan and Security Agreement between Encision Inc. and Crestmark Bank dated March 15, 2016 \(incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K filed on June 14, 2016\).](#)
- 10.7 [Fifth Amendment to Office Building Lease dated November 9, 2017 \(Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed February 12, 2018\).](#)
- 10.8 [Loan Agreement between Encision Inc. and Bank of America dated July 31, 2018 \(incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on August 13, 2018\).](#)
- 10.9 [Securities Purchase Agreement dated December 19, 2018 \(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 3, 2019\).](#)
- 31.1 [Section 302 Certification of Principal Executive Officer**](#)

31.2 [Section 302 Certification of Principal Financial and Accounting Officer](#) **

32.1 [Section 906 Certifications](#) **

† Denotes management contract or compensatory plan or arrangement.

** Filed herewith.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENCISION INC.

Dated: June 14, 2019

By: /s/ Mala Ray
Mala Ray
Controller
Principal Accounting Officer & Principal Financial Officer

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

<u>Signature</u>	<u>Date</u>
<u>/s/ Mala Ray</u> Mala Ray Controller Principal Accounting Officer & Principal Financial Officer	June 14, 2019
<u>/s/ Patrick W. Pace</u> Patrick W. Pace Director	June 14, 2019
<u>/s/ Robert H. Fries</u> Robert H. Fries Director	June 14, 2019
<u>/s/ Vern D. Kornelsen</u> Vern D. Kornelsen Director	June 14, 2019
<u>/s/ Gregory J. Trudel</u> Gregory J. Trudel President and CEO Principal Executive Officer Director	June 14, 2019
<u>/s/ David W. Newton</u> David W. Newton Vice President - Technology Director	June 14, 2019

DESCRIPTION OF CAPITAL STOCK

The following summary description of the securities is not complete and is qualified in its entirety by reference to our articles of incorporation, as amended, our bylaws and applicable provisions of Colorado corporation law.

Our authorized capital stock consists of 110,000,000 shares of capital stock without par value, of which 100,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

Common Stock

The holders of the common stock (i) have equal ratable rights to dividends from funds legally available therefor, when, as and if declared by our Board of Directors; (ii) are entitled to share ratably in all Encision assets available for distribution to holders of the common stock upon liquidation, dissolution or winding up of our affairs; (iii) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions applicable thereto; and (iv) are entitled to one vote per share on all matters which shareholders may vote on at all meetings of shareholders. All shares of the common stock now outstanding are fully paid and nonassessable.

The holders of common stock do not have cumulative voting rights, which means that the holders of more than 50 percent of such outstanding shares voting for the election of directors can elect all of our directors to be elected; if they so choose. In such event, the holders of the remaining shares will not be able to elect any of our directors.

Preferred Stock

Under governing Colorado law and our Articles of Incorporation, no action by our shareholders is necessary, and only action of the Board of Directors is required, to authorize the issuance of any of the preferred stock. Our Board of Directors is empowered to establish and to designate the name of each class or series of the shares and to set the terms of such shares (including terms with respect to redemption, sinking fund, dividend, liquidation, preemptive, conversion and voting rights and preferences). Accordingly, our Board of Directors, without shareholder approval, may issue preferred stock with terms (including terms with respect to redemption, sinking fund, dividend, liquidation, preemptive, conversion and voting rights and preferences) that could adversely affect the voting power and other rights of holders of the common stock.

The existence of preferred stock may have the effect of discouraging an attempt, through acquisition of a substantial number of shares of common stock, to acquire control of us with a view to affecting a merger, sale or exchange of assets or a similar transaction. The anti-takeover effects of the preferred stock may deny shareholders the receipt of a premium on their common stock and may also have a depressive effect on the market price of the common stock.

Advance Notice Provisions of Our Bylaws

Our bylaws contain advance notice procedures for stockholders to call a special meeting of stockholders, to make nominations of candidates for election as directors or to bring other business before the annual meeting of stockholders.

CERTIFICATIONS

I, Gregory Trudel, certify that:

1. I have reviewed this annual report on Form 10-K of Encision Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and,
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: June 14, 2019

/s/ Gregory Trudel

Gregory Trudel
President and CEO

CERTIFICATIONS

I, Mala Ray, certify that:

1. I have reviewed this annual report on Form 10-K of Encision Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and,
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: June 14, 2019

/s/ Mala Ray

Mala Ray
Controller, Principal Accounting Officer and Principal Financial Officer

CERTIFICATIONS OF PERIODIC REPORT

I, Gregory Trudel, President and Chief Executive Officer of Encision Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the annual period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: June 14, 2019

/s/ Gregory Trudel
Gregory Trudel
President and Chief Executive
Officer

I, Mala Ray, Controller, Principal Accounting Officer and Principal Financial Officer of Encision Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the annual period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: June 14, 2019

/s/ Mala Ray
Mala Ray
Controller, Principal Accounting Officer and Principal Financial
Officer