MISONIX INC
Form 10-K
February 09, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 1-10986

MISONIX, INC.
(Exact name of registrant as specified in its charter)

New York	11-2148932

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1938 New Highway, Farmingdale, New York (Address of principal executive offices)	11735 (Zip Code)

Registrant's telephone number, including area code: (631) 694-9555

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

Title of each class	Name of each exchange on which registered
Common Stock, $.01 par value	Nasdaq Global Market

Securities registered pursuant to 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 þ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

¨ Yes þ 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 Securities Exchange Act of 1934 during the preceding 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 þ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ¨ Yes þ 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. þ

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

¨ Yes þ No

The aggregate market value of the voting stock held by non-affiliates of the registrant on December 31, 2015 (computed by reference to the closing price of such stock on such date) was approximately $62,107,436.

There were 9,008,354 shares of Common Stock outstanding at February 1, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

None

USE OF FORWARD-LOOKING STATEMENTS

In this document, we refer to Misonix, Inc. and its subsidiaries (unless the context otherwise requires) as “we,” the “Company” or “Misonix.” With the exception of historical information contained in this Form 10-K, content herein may contain "forward looking statements" that are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. We cannot guarantee that any forward looking statements will be accurate, although we believe that we have been reasonable in our expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from our expectations and projections. These factors include general economic conditions, delays and risks associated with the performance of contracts, risks associated with international sales and currency fluctuations, uncertainties as a result of research and development, acceptable results from clinical studies, including publication of results and patient/procedure data with varying levels of statistical relevance, risks involved in introducing and marketing new products, regulatory compliance, potential acquisitions, consumer and industry acceptance, litigation and/or contemplated 510(k) filings, the ability to achieve and maintain profitability in our business lines, and other factors discussed in this Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We disclaim any obligation to update any forward-looking statements.

TABLE OF CONTENTS

Explanatory Note

We were not able to file this Annual Report on Form 10-K (the "10-K") for the fiscal year ended June 30, 2016 by its due date. For several months, with the assistance of outside counsel, we have been conducting a voluntary investigation into the business practices of the independent Chinese entity that previously distributed our products in China and the Company's knowledge of those business practices, which may have implications under the Foreign Corrupt Practices Act ("FCPA"), as well as into various internal controls issues identified during the investigation (the "Investigation"). On September 27, 2016 and September 28, 2016, we voluntarily contacted the Securities and Exchange Commission ("SEC") and the U.S. Department of Justice ("DOJ"), respectively, to advise both agencies of these potential issues. We have provided and will continue to provide documents and other information to the SEC and the DOJ, and are cooperating fully with these agencies in their investigations of these matters.

Although our Investigation is now complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. We could also receive additional requests from the DOJ or SEC, which may require further investigation. We have no current information derived from the Investigation or otherwise to suggest that our previously reported financial statements and results are incorrect.

Our management has determined, because of the findings from the Investigation, and the Company's inability to rely on certain personnel, processes and internal controls, that material weaknesses in internal control over financial reporting existed at June 30, 2016. In light of such material weaknesses, management has concluded that the Company's internal control over financial reporting was ineffective as of June 30, 2016. We have since implemented the changes, controls and procedures as described in Item 9A which we believe are necessary to remediate these weaknesses.

On September 15, 2016, we received a deficiency letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company, as a result of not filing the 10-K on September 13, 2016 and disclosing that the Company likely would not be able to file the 10-K within the 15-day extension period provided in Rule 12b-25(b) under the Securities Exchange Act of 1934, as amended, was not in compliance with Listing Rule 5250(c)(1) of the Nasdaq Listing Rules (the "Rules") for continued listing. In addition, on November 10, 2016, we received a second deficiency letter from Nasdaq indicating that the Company, as a result of not filing our Quarterly Report on Form 10-Q (the "10-Q") by November 9, 2016, together with our prior and ongoing failure to timely file the 10-K, was not in compliance with Listing Rule 5250(c)(1) for continued listing. In the letters, Nasdaq requested that Misonix submit a plan to regain compliance with the Rules by November 14, 2016. On November 14, 2016, Misonix submitted to Nasdaq a plan to regain compliance with the Rules. After reviewing Misonix's plan to regain compliance, Nasdaq granted an exception to enable the Company to regain compliance with the Rules. Under the terms of the exception, Misonix must file its 10-K and 10-Q on or before March 13, 2017. In the event that Misonix does not satisfy the terms set forth in the extension, Nasdaq will provide written notification that Misonix's common stock will be delisted. At that time, Misonix may appeal Nasdaq's determination for a panel review.

See Item 3 “Legal Proceedings”, Item 5 “Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities” and Item 9A “Controls and Procedures” for additional information regarding these matters.

PART I

Item 1. Business

Overview

Misonix, Inc. is a New York corporation which, through its predecessors, was first organized in 1959. We design, manufacture, develop and market minimally invasive therapeutic ultrasonic medical devices. Our products enhance clinical outcomes and provide value to the overall healthcare system. Since we commercialized our ultrasonic vessel sealing system with US Surgical in 1996, we have helped create a multi-billion dollar segment within the overall general surgical and gynecological arena. We believe that our current focus products have the ability to become standard of care and provide the Company with a steady recurring revenue stream.

- BoneScalpel ® surgical system ("BoneScalpel"), is used mainly for surgical procedures involving the precise cutting of bone while sparing soft tissue. BoneScapel is now recognized by surgeons globally as one of the most important surgical devices enabling improved patient outcomes in the spinal arena.

- SonaStar ® Surgical Aspirator ("SonaStar"), which is used to emulsify and remove soft and hard tumors, primarily in the neuro and general surgery field.

- SonicOne® Wound Cleansing and Debridement System ("SonicOne"), which offers tissue specific debridement and cleansing of wounds and burns for effective removal of devitalized tissue and fibrin deposits while sparing viable cells.

These devices primarily serve the following clinical specialties: neurosurgery, orthopedic surgery, plastic surgery, wounds, burn and maxillo-facial.

In the United States, our products are marketed primarily through a hybrid sales approach. This includes contracted, commissioned, independent sales representatives, managed by regional sales managers and supported by Company application specialists.

Outside the United States, we sell BoneScalpel and SonaStar to specialty distributors who purchase products from us to resell to their clinical customer bases. We sell to all major markets in the Americas, Europe, Middle East, Asia Pacific and Africa.

Products

All Misonix disposables function with proprietary consoles which essentially convert electrical current into ultrasonic energy via piezo electric crystals in order for the relevant device to produce a therapeutic effect.

BoneScalpel

The BoneScalpel is a state of the art, ultrasonic bone cutting system capable of making precise cuts with minimal necrosis, minimal burn artifact, minimal inflammation and minimal bone loss. The device is also capable of preserving surrounding soft tissue structures because of its unique ability to differentiate soft tissue from rigid bone. This device can make precise linear or curved cuts, on any plane, with precision not normally associated with powered instrumentation. The BoneScalpel offers the speed and convenience of a powered instrument without the dangers associated with conventional rotary devices. The effect on surrounding soft tissue is minimal due to the elastic and flexible structure of healthy tissue. This is a significant advantage in anatomical regions like the spine where patient safety is of primary concern. In addition, the linear motion of the blunt, tissue-impacting tips avoids accidental ‘trapping’ of soft tissue while largely eliminating the high speed spinning and tearing associated with rotary power instruments. The BoneScalpel allows surgeons to improve on existing surgical techniques by creating new approaches to bone cutting and removal, leading to substantial time savings and increased operation efficiencies. Following its introduction in 2012, BoneScalpel sales have achieved an average annual growth rate of 28.4%.

The expanded BoneScalpel product platform will allow entry into dynamic market segments like MIS spine surgery. In the future, additional market niche opportunities may exist in small bone surgery of the hand, foot or ankle.

SonaStar

The SonaStar system provides powerful precise aspiration following the ultrasonic ablation of hard or soft tissue. The SonaStar has been used for a wide variety of surgical procedures applying both open and minimally invasive approaches, including neurosurgery and liver surgery. The SonaStar may also be used with OsteoSculpt ® probe tips, which enable the precise shaping or shaving of bony structures that prevent open access to partially or completely hidden soft tissue masses.

SonicOne

The SonicOne Ultrasonic Cleansing and Debridement System is a highly innovative, tissue specific approach for the effective removal of devitalized or necrotic tissue and fibrin deposits while sparing viable, surrounding cellular structures. The tissue specific capability is, in part, due to the fact that healthy and viable tissue structures have a higher elasticity and flexibility than necrotic tissue and are more resistant to destruction from the impact effects of ultrasound. The ultrasonic debridement process separates devitalized tissue from viable tissue layers, allowing for a more defined treatment and, usually, a reduced pain sensation. We believe SonicOne establishes a new standard in wound and burn bed preparation, the essential first step in the healing process, while contributing to a faster patient healing.

Other Business and Medical Devices

In October 1996, we entered into a license agreement with Medtronic Minimally Invasive Therapies (“MMIT”). The MMIT license covers the further development of our medical technology relating to vessel sealing products, which uses high frequency sound waves to coagulate and divide tissue for both open and laparoscopic surgery. We developed the AutoSonix product with MMIT under the agreement. As a result of this joint development, we co-own certain patents with MMIT and MMIT pays us a 5% royalty on end user sales. The MMIT license gives MMIT exclusive worldwide marketing and sales rights for this technology and device. Total royalties from sales of this device worldwide were approximately $3,903,000, $4,162,000 and $3,619,000 for the fiscal years ended June 30, 2016, 2015 and 2014, respectively. The royalty is recorded as “other income” in our financial statements. Our license agreement with MMIT expires in August 2017.

High Intensity Focused Ultrasound Technology

We sold our rights to the high intensity focused ultrasound technology to SonaCare Medical, LLC ("SonaCare") in May 2010. We may receive up to approximately $5.8 million in payment for the sale. SonaCare will pay us 7% of the gross revenues received from its sales of the (i) prostate product in Europe and (ii) kidney and liver products worldwide, until we have received payments of $3 million, and thereafter 5% of the gross revenues, up to an aggregate payment of $5.8 million. Cumulative payments through June 30, 2016 were $1,254,788.

Other

The Company's distribution agreement with Mentor Corporation, a subsidiary of Johnson & Johnson, for the sale, marketing and distribution of the Lysonix soft tissue aspirator used for cosmetic surgery has terminated. Sales continue on a limited non-contractual purchase order basis. Total sales of this device, which includes parts and service, were approximately $45,000, $264,000 and $343,000 for the fiscal years ended June 30, 2016, 2015 and 2014, respectively.

Customers

For the fiscal years ended June 30, 2016, 2015 and 2014, Cicel (Beijing) Science and Tech Co. Ltd., the Company's former Chinese distributor, accounted for 6.4%, 13.4% and 14.6% of the Company's net sales, respectively. We did not have any other customer that accounted for 10% or more of our net sales during such periods.

Research & Development

As of June 30, 2016, our Research and Development ("R&D") organization consisted of a staff of nine employees including engineers, technical and support personnel. The in-house technical expertise includes mechanical engineering, acoustics, electrical engineering, software development and product design. The R&D group focuses principally on developing new products and supporting existing products.

During the three years ended June 30, 2016, the Company incurred R&D expenses of $1,670,347, $1,592,923 and $1,711,571, or 7.2%, 7.2% and 10.0% of sales, respectively.

Revenue by Region

The Company's revenues are generated from various regions throughout the world. Sales by the Company outside the United States are made through distributors. Sales made in the United States are made primarily through representative agents. The following is an analysis of net sales from continuing operations by geographic region:

	For the years ended June 30,			Net Change	
	2016	2015	2014	2016	2015
Domestic	$13,086,806	$10,797,920	$8,185,468	21.2 %	31.9%
International	10,026,388	11,406,658	8,874,967	-12.1%	28.5%
Total	$23,113,194	$22,204,578	$17,060,435	4.1 %	30.2%

Our international sales include a concentration in China, aggregating $1,557,132, $2,974,086 and $2,495,960, for the fiscal years ended June 30, 2016, 2015 and 2014, respectively.

Manufacturing and Supply

The Company manufactures and assembles its medical device products at its production facility located in Farmingdale, New York. The Company's products include components manufactured by other companies in the United States. The Company is not dependent upon any single source of supply and has no long-term supply agreements. The Company believes that it will not encounter difficulty in obtaining materials, supplies and components adequate for its anticipated short-term needs.

Competition

Competition in the medical device products industry is rigorous with many companies having significant capital resources, large research laboratories and extensive distribution systems greater than the Company's. Some of the Company's major competitors are Medtronic, Anspach, Johnson & Johnson, Integra Life Sciences, Inc., Söering, Stryker Corporation and Smith and Nephew.

Regulatory Requirements

The Company's medical device products are subject to the regulatory requirements of the U.S. Food and Drug Administration (“FDA”) and other international regulatory authorities. In the United States and other markets where the Company's products are sold, the Company has the appropriate marketing authorizations and complies with all applicable regulations.

The Company also operates and maintains a Quality Management System which complies with the requirements of International Standards ISO 13485: 2003 + AC:2007, MDD 93/42EEC, Canadian MDR: 2003, and the FDA’s Good Manufacturing Practices: cGMP’s 21CFR Part 820. This system encompasses the principles of identifying, monitoring, controlling and enhancing to continuously improve our work processes, including product complaints. Current Misonix products have 510(k) clearances.

The Company is not aware of any regulatory situations, other than those disclosed in Item 3 herein, that would materially impact the Company, nor is the Company aware of any pending legal action or new material breaches of the regulations to which it is subject.

Trademarks, Patents, and Copyrights

The Company holds 54 U.S. patents along with 11 in Europe, 8 in Japan and 11 in Canada and has multiple pending patent applications for its core product lines including ultrasonic and wound technologies, among other things. The Company believes that these patents provide it with a competitive market advantage. The Company also holds 7 trademarks protecting its Company and product names.

The Company will continue to seek patent, trademark, and copyright protections as it deems advisable to protect the markets for its products and its R&D efforts.

Backlog

As of June 30, 2016, the Company's backlog (firm orders that have not yet been shipped) was $45,256, as compared to $33,238 as of June 30, 2015. The Company does not typically have large recurring orders, but instead ships most of its

products on a just in time basis, which results in low levels of backlog.

Employees

As of June 30, 2016, the Company employed a total of 85 full-time employees, including 40 in management and supervisory positions. The Company considers its relationship with its employees to be good.

Website Access Disclosure

The Company's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K are available free of charge on the Company's website at www.misonix.com as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Copies of the Company's Annual Report will be made available to shareholders, free of charge, upon written request.

Item 1A. Risk Factors.

In addition to the other information contained in the 10-K and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition and/or results of operations could be materially adversely affected by any of these risks. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements set forth immediately prior to the beginning of Item 1 of the 10-K. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition and/or results of operations. The following list sets forth many, but not all, of the factors that could impact the Company's ability to achieve results discussed in any forward-looking statement. Investors should understand that it is not possible to predict or identify all such factors and should not consider this list to be a complete statement of all potential risks and uncertainties.

Risks Related to Our Business

The termination of our former Chinese distributor will have an adverse effect on our sales revenue.

For the fiscal years ended June 30, 2016, 2015 and 2014, our former Chinese distributor accounted for 6.4%, 13.4% and 14.6% of our net sales, respectively. This distributor was our largest single customer for the last three fiscal years. We have ended our commercial relationship with this distributor in 2016 due to allegations of potential violation of laws (See Item 3 "Legal Proceedings"). The termination of this distributor will have an adverse effect on our net sales and there can be no assurance that we will be able to replace such revenues in the near term or at all.

We have identified material weaknesses in our disclosure controls and procedures and internal control over financial reporting. If not remediated, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our common stock.

Management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of June 30, 2016, based on the criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon this evaluation, management has determined, because of the findings from the Investigation, and the Company's inability to rely on certain personnel, processes and internal controls, that material weaknesses existed at June 30, 2016. In light of such material weaknesses, management has concluded that the Company's internal control over financial reporting was ineffective as of June 30, 2016. In addition, the Company has concluded that, as of such date, there were material weaknesses in the

Company’s disclosure controls and procedures as a result of the material internal control weaknesses.

Maintaining effective disclosure controls and procedures and effective internal control over financial reporting are necessary for us to produce reliable financial statements and the Company is committed to remediating its material weaknesses in such controls as promptly as possible. The implementation of the Company’s remediation plans has commenced (see Item 9A. “Controls and Procedures” in the 10-K for additional information regarding such material weaknesses and such remediation process). However, there can be no assurance that such material weaknesses will be remediated or that additional material weaknesses will not arise in the future. Any failure to remediate such material weaknesses, or the development of new material weaknesses in our disclosure controls and procedures or internal control over financial reporting, could result in material misstatements in our financial statements and cause us to fail to meet our reporting and financial obligations, which in turn could have a material adverse effect on our business, financial condition and the trading price of our common stock.

We are subject to extensive medical device regulation which may impede or hinder the approval process for our products and, in some cases, may not ultimately result in approval or may result in the recall or seizure of previously approved products.

Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation in the United States by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDC Act, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S. In addition, most major markets for medical devices outside the U.S. require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining marketing approval or clearance from the FDA for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant amount of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to the products; and
- result in limitations on the proposed uses of the products.

Marketing approvals or clearances are not the only risk. The FDA, and other regulatory bodies, also can require the withdrawal of an approved or cleared product from commercial distribution due to failure to comply with regulatory standards or the occurrence of unforeseen problems.

As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, FDA regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a medical device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Union and China, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to meet regulatory quality standards could have a material adverse effect on our business, financial condition or results of operations.

Consequently, there can be no assurance that we will receive the required clearances from the FDA or other regulatory bodies for new products or modifications to existing products on a timely basis or that any FDA approval will not be subsequently withdrawn. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and/or criminal prosecution. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products or the withdrawal of product approval by the FDA or other regulatory bodies could have a material adverse effect on our business, financial condition or results of operations.

We may not be able to effectively protect our intellectual property rights.

Patents and other proprietary rights are and will be essential to our business and our ability to compete effectively with other companies. We also rely upon trade secrets, know-how, continuing technological innovations, strategic alliances and licensing opportunities to develop, maintain and strengthen our competitive position. We pursue a policy of generally obtaining patent protection in both the U.S. and abroad for patentable subject matter in our proprietary devices and also attempt to review third-party patents and patent applications to the extent publicly available to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. We currently own numerous U.S. and foreign patents. We also are party to

various license agreements pursuant to which patent rights have been obtained or granted in consideration for cash or royalty payments. No assurance can be made that any pending or future patent applications will result in issued patents, that any current or future patents issued to, or licensed by, us will not be challenged or circumvented by our competitors, or that our patents will not be found invalid.

We also operate in an industry that is susceptible to significant intellectual property litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the patent rights of other companies in order to prevent the marketing of new devices. Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. Future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may significantly divert the attention of our technical and management personnel.

In addition, we may have to take legal action in the future to protect our patents, trade secrets or know-how or to assert our intellectual property rights against claimed infringement by others. Any legal action of that type could be costly and time consuming to us and no assurances can be made that any lawsuit will be successful.

The invalidation of key patents or proprietary rights that we own, or an unsuccessful outcome in lawsuits to protect our intellectual property, could have a material adverse effect on our business, financial condition or results of operations. In the event that our right to market any of our products is successfully challenged, or if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected.

Future product liability claims and other litigation may adversely affect our business, reputation and ability to attract and retain customers.

The design, manufacture and marketing of medical device products of the types that we produce entail an inherent risk of product liability claims. A number of factors could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we manufacture or sell, including component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information. These factors could result in product liability claims, a recall of one or more of our products or a safety alert relating to one or more of our products. Product liability claims may be brought by individuals or by groups seeking to represent a class.

Anyone or any company can bring an action against Misonix, including private securities litigation and shareholder derivative suits, and adverse litigation results could affect our business.

Our judicial system allows anyone, including shareholders, to bring a claim against the Company and force the Company to defend itself even if the claim is baseless. The defense may or may not be covered by the Company's insurance, the result of which could ultimately create a burden on the Company dependent upon the outcome.

Litigation can be lengthy, expensive and disruptive to our operations, and results cannot be predicted with certainty. An adverse decision could result in monetary damages or injunctive relief that could affect our financial condition or results of operations.

On September 19, 2016, Richard Scalfani, an individual shareholder of Misonix, filed a lawsuit against the Company and its former CEO and CFO in the U.S. District Court for the Eastern District of New York, alleging violations of the

federal securities laws. The complaint alleges that the Company's stock price was artificially inflated between November 5, 2015 and September 14, 2016 as a result of alleged false and misleading statements in the Company's securities filings concerning the Company's business, operations, and prospects and the Company's internal control over financial reporting. Scalfani filed the action seeking to represent a putative class of all persons (other than defendants, officers and directors of the Company, and their affiliates) who purchased publicly traded Misonix securities between November 5, 2015 and September 14, 2016. Scalfani seeks an unspecified amount of damages for himself and for the putative class under the federal securities laws. On November 18, 2016, Scalfani and another individual Misonix shareholder, Tracey Angiuoli, moved the Court to be appointed lead plaintiffs for purposes of pursuing the action on behalf of the putative class.

Violation of anti-corruption laws could subject the Company to significant penalties which would materially affect our business and liquidity.

We are required to comply with the FCPA and similar anti-corruption laws in other jurisdictions around the world where we do business. Compliance with these laws has been subject to increasing focus and activity by regulatory authorities in recent years. Actions by our employees, or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere in connection with the conduct of our business may expose us to liability for violations of the FCPA or other anti-corruption laws and accordingly may have a material adverse effect on our reputation and our business, financial condition or results of operations.

For several months, with the assistance of outside counsel, the Company has been conducting the Investigation into the business practices of the independent Chinese entity that previously distributed its products in China and the Company's knowledge of those business practices, which may have implications under the FCPA, as well as into various internal controls issues identified during the Investigation.

On September 27, 2016 and September 28, 2016, we voluntarily contacted the SEC and the DOJ, respectively, to advise both agencies of these potential issues. We have provided and will continue to provide documents and other information to the SEC and the DOJ, and are cooperating fully with these agencies in their investigations of these matters.

Although our Investigation is complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. The Company could also receive additional requests from the DOJ or SEC, which may require further investigation. The Company has no current information derived from the Investigation or otherwise to suggest that its previously reported financial statements and results are incorrect.

At this stage, the Company is unable to predict what, if any, action the DOJ or the SEC may take or what, if any, penalties or remedial measures these agencies may seek. Nor can we predict the impact on the Company as a result of these matters, which may include the cost of investigations, defense, imposition of fines, civil and criminal penalties, which are not currently estimable, as well as equitable remedies, including disgorgement of any profits earned from improper conduct and injunctive relief, limitations on the Company's conduct, and the imposition of a compliance monitor. The DOJ and the SEC periodically have based the amount of a penalty or disgorgement in connection with an FCPA action, at least in part, on the amount of profits that a company obtained from the business in which the violations of the FCPA occurred. Since the inception of its distributorship relationship with the prior Chinese distributor in 2012, the Company has generated sales of approximately $8 million from the relationship. We cannot assure you that the DOJ and the SEC will not impose penalties based on the profit derived from these sales.

Further, we may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuit that has already been filed, or investigations and fines imposed by local authorities.

We are not in compliance with the requirements of Nasdaq for continued listing, and if Nasdaq does not concur that we have adequately remedied our non-compliance with Nasdaq Listing Rule 5250(c)(1), our common stock may be delisted from trading on Nasdaq, which could have a material adverse effect on us and our shareholders.

On September 15, 2016, we received a deficiency letter from Nasdaq indicating that the Company, as a result of not filing the 10-K on September 13, 2016 and disclosing that the Company likely would not be able to file the 10-K within the 15-day extension period provided in Rule 12b-25(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), was not in compliance with Listing Rule 5250(c)(1) of the Rules for continued listing. In addition, on November 10, 2016, the Company received a second deficiency letter from Nasdaq indicating that the Company, as a result of not filing the 10-Q by November 9, 2016, together with its prior and ongoing failure to timely file the 10-K, was not in compliance with Listing Rule 5250(c)(1) for continued listing. In the letters, Nasdaq requested that Misonix submit a plan to regain compliance with the Listing Rules by November 14, 2016.

On November 14, 2016, Misonix submitted to Nasdaq a plan to regain compliance with the Rules. After reviewing Misonix's plan to regain compliance, Nasdaq granted an exception to enable the Company to regain compliance with the Rules. Under the terms of the exception, Misonix must file the 10-K and the 10-Q on or before March 13, 2017. In the event that Misonix does not satisfy the terms set forth in the extension, Nasdaq will provide written notification that Misonix's common stock will be delisted. At that time, Misonix may appeal Nasdaq's determination for a panel review.

There can be no assurance that Nasdaq will concur that we have remedied our non-compliance with Listing Rule 5250(c)(1), in which case our common stock could remain subject to delisting by Nasdaq. If our common stock were delisted, there can be no assurance whether or when it would again be listed for trading on Nasdaq or any other securities exchange. In addition, the market price of our shares might decline and become more volatile, and our shareholders might find that their investment in our shares has limited liquidity. Furthermore, institutions whose charters do not allow them to hold securities in unlisted companies might sell our shares, which could have a further adverse effect on the price of our stock.

As a result of the delayed filing of our Quarterly Report on Form 10-Q for the fiscal period ended September 30, 2016 and this Annual Report on Form 10-K with the SEC, we are not currently eligible to use a registration statement on Form S-3 to register the offer and sale of securities, which may adversely affect our ability to raise future capital or complete acquisitions.

We are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3 and we will not become eligible until we have timely filed certain periodic reports required under the Exchange Act for 12 consecutive calendar months. There can be no assurance when we will meet this requirement, which depends in part upon our ability to file our periodic reports on a timely basis in the future. Should we wish to register the offer and sale of our securities to the public before we are eligible to do so on Form S-3, our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially having an adverse effect on our financial condition.

Our future growth is dependent upon the development of new products and line extensions, which requires significant research and development, clinical trials and regulatory approvals, all of which are very expensive and time-consuming and may not result in a commercially viable product.

In order to develop new products and improve current product offerings, we focus our research and development programs largely on the development of next-generation and novel technology offerings across multiple programs and opportunities.

As a part of the regulatory process of obtaining marketing clearance from the FDA for new products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors or by third parties, or the market's perception of this clinical data, may adversely impact our ability to obtain product approvals from the FDA, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

New products may not be accepted by customers in the marketplace.

We are now, and will continue to be, developing new products and introducing them into the market. There can be no assurance that any new product will be accepted by the market. New products are sometimes introduced into the market in a prototype format and may need later revisions or design changes before they operate in a manner to be accepted in the market. As a result of the introduction of new products, there is some risk that revenue expectations may not be met and in some cases the product may not achieve market acceptance.

We face intense competition and may not be able to keep pace with the rapid technological changes in the medical device industry.

The medical device product market is highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies, most of which have greater financial and marketing resources than we do.

Additionally, the medical device product market is characterized by extensive research and development and rapid technological change. Developments by other companies of new or improved products, processes or technology may make our products or proposed products obsolete or less competitive and may negatively impact our revenues. In some cases foreign companies may attempt to copy our designs illegally. We are required to devote continued efforts and financial resources to develop or acquire scientifically advanced technologies and products, apply our technologies cost-effectively across product lines and markets, attract and retain skilled development personnel, obtain patent and other protection for our technology and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products. Failure to develop new products or enhance existing products could have a material adverse effect on our business, financial condition or results of operations.

Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from certain of our significant market segments.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payers to curb these costs have resulted in a consolidation trend in the healthcare industry, including hospitals. This in turn has resulted in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or results of operations.

We may experience disruption in supply due to our dependence on our suppliers to continue to ship product requirements and our inability to obtain suppliers of certain components for our products.

Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunctions, labor shortages or environmental factors. In addition, we purchase both raw materials used in our products and finished goods from various suppliers and may have to rely on a single source supplier for certain components of our products where there are no alternatives are available. Although we anticipate that we have adequate sources of supply and/or inventory of these components to handle our production needs for the foreseeable future, if we are unable to secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find suppliers at an acceptable cost, then the manufacture of our products may be disrupted, which could increase our costs and have a material adverse effect on our business.

If we fail to manage any expansion or acquisition, our business could be impaired.

We may in the future acquire one or more technologies, products or companies that complement our business. We may not be able to effectively integrate these into our business and any such acquisition could bring additional risks, exposures and challenges to the Company. In addition, acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities and increase our risk of litigation, all of which could harm our business. If we use cash to acquire technologies, products, or companies, such use may divert resources otherwise available for other purposes. If we use our common stock to acquire technologies, products, or companies, our shareholders may experience substantial dilution. If we fail to manage any expansions or acquisition, our business could be impaired.

Our agreements and contracts entered into with partners and other third parties may not be successful.

We signed in the past and may pursue in the future agreements and contracts with third parties to assist in our marketing, manufacturing, selling and distribution efforts. We cannot assure you that any agreements or contracts entered into will be successful.

The fluctuation of our quarterly results may adversely affect the trading price of our common stock.

Our revenues and results of operations have in the past and will likely vary in the future from quarter to quarter due to a number of factors, many of which are outside of our control and any of which may cause our stock price to fluctuate. You should not rely on quarter-to-quarter comparisons of our results of operations as an indication of our future performance. It is likely that in some future quarters, our results of operations may be below the expectations of public market analysts and investors. In this event, the price of our common stock may fall.

We may not be able to attract and retain additional key management, sales and marketing and technical personnel, or we may lose existing key management, sales and marketing or technical personnel, which may delay our development and marketing efforts.

We depend on a number of key management, sales and marketing and technical personnel. The loss of the services of one or more key employees could delay the achievement of our development and marketing objectives. Our success will also depend on our ability to attract and retain additional highly qualified management, sales and marketing and technical personnel to meet our growth goals. We face intense competition for qualified personnel, many of whom are often subject to competing employment offers, and we do not know whether we will be able to attract and retain such personnel.

Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse or unexpected revenue fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our

business.

The Affordable Healthcare for America Act includes provisions that may adversely affect our business and results of operations, including an excise tax on the sales of most medical devices.

On March 21, 2010, the House of Representatives passed the Affordable Health Care for America Act, which President Obama signed into law on March 23, 2010. With a new administration in place beginning in 2017, changes may be made to the Affordable Health Care Act, or it may be repealed and replaced. The potential impact of these events may adversely affect our business and results of operations. The medical device tax has been established, but in the future the government may decide to increase the tax rate. The impact of the recent change in Presidential administration has yet to be determined.

We are experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater regulation in the future.

Our medical devices and our business activities are subject to rigorous regulation, including by the FDA, the DOJ and numerous other federal, state and foreign governmental authorities. These authorities and members of Congress have been increasing their scrutiny of our industry. Certain state governments and the federal government have enacted legislation aimed at increasing transparency of our interactions with health care providers. As a result, we are required by law to disclose payments and other transfers of value to health care providers licensed by certain states and, starting with payments or other transfers of value made on or after August 1, 2013, to all U.S. physicians and U.S. teaching hospitals at the federal level. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we may continue to devote substantial additional time and financial resources to further develop and implement policies, systems, and processes to comply with enhanced legal and regulatory requirements, which may also impact our business. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects on our operations.

Risk of reprocessing disposables.

In some jurisdictions around the world, culture and practice encourages reuse of disposable products when the product is clearly labeled for single use. Such reuse may expose us to liability in these jurisdictions.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company occupies approximately 34,400 square feet at 1938 New Highway, Farmingdale, New York pursuant to a lease expiring on June 30, 2018. The Company pays rent of approximately $26,000 a month, which includes a pro rata share of real estate taxes, water, sewer and other charges which are assessed on the leased premises or the land upon which the leased premises are situated. The Company believes that the leased facilities are adequate for its present needs.

Item 3. Legal Proceedings.

Former Chinese Distributor

For several months, with the assistance of outside counsel, the Company has been conducting the Investigation into the business practices of the independent Chinese entity that previously distributed its products in China and the Company's knowledge of those business practices, which may have implications under the FCPA, as well as into various internal controls issues identified during the Investigation.

On September 27, 2016 and September 28, 2016, we voluntarily contacted the SEC and the DOJ, respectively, to advise both agencies of these potential issues. We have provided and will continue to provide documents and other information to the SEC and the DOJ, and are cooperating fully with these agencies in their investigations of these

matters.

Although our Investigation is complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. The Company could also receive additional requests from the DOJ or SEC, which may require further investigation. The Company has no current information derived from the Investigation or otherwise to suggest that its previously reported financial statements and results are incorrect.

At this stage, the Company is unable to predict what, if any, action the DOJ or the SEC may take or what, if any, penalties or remedial measures these agencies may seek. Nor can we predict the impact on the Company as a result of these matters, which may include the cost of investigations, defense, imposition of fines, civil and criminal penalties, which are not currently estimable, as well as equitable remedies, including disgorgement of any profits earned from improper conduct and injunctive relief, limitations on the Company's conduct, and the imposition of a compliance monitor. The DOJ and the SEC periodically have based the amount of a penalty or disgorgement in connection with an FCPA action, at least in part, on the amount of profits that a company obtained from the business in which the violations of the FCPA occurred. Since the inception of its distributorship relationship with the prior Chinese distributor in 2012, the Company has generated sales of approximately $8 million from the relationship.

Further, we may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuit that has already been filed, or investigations and fines imposed by local authorities.

Class Action Securities Litigation

On September 19, 2016, Richard Scalfani, an individual shareholder of Misonix, filed a lawsuit against the Company and its former CEO and CFO in the U.S. District Court for the Eastern District of New York, alleging violations of the federal securities laws. The complaint alleges that the Company's stock price was artificially inflated between November 5, 2015 and September 14, 2016 as a result of alleged false and misleading statements in the Company's securities filings concerning the Company's business, operations, and prospects and the Company's internal control over financial reporting. Scalfani filed the action seeking to represent a putative class of all persons (other than defendants, officers and directors of the Company, and their affiliates) who purchased publicly traded Misonix securities between November 5, 2015 and September 14, 2016. Scalfani seeks an unspecified amount of damages for himself and for the putative class under the federal securities laws.

On November 18, 2016, Scalfani and another individual Misonix shareholder, Tracey Angiuoli, moved the Court to be appointed lead plaintiffs for purposes of pursuing the action on behalf of the putative class.

The Company believes it has various legal and factual defenses to the allegations in the complaint, and intends to vigorously defend the action. The case is at its earliest stages; there has been no discovery and there is no trial date.

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.

The Company's common stock, $.01 par value ("Common Stock"), is listed on the Nasdaq Global Market under the symbol "MSON".

On September 15, 2016, the Company received a deficiency letter from The Nasdaq Stock Market LLC indicating that the Company, as a result of not filing the 10-K on September 13, 2016 and disclosing that the Company likely would not be able to file the 10-K within the 15-day extension period provided in Rule 12b-25(b) under the Exchange Act was not in compliance with Listing Rule 5250(c)(1) of the Rules for continued listing. In addition, on November 10, 2016, the Company received a second deficiency letter from Nasdaq indicating that the Company, as a result of not filing the 10-Q by November 9, 2016, together with its prior and ongoing failure to timely file the 10-K, was not in compliance with Listing Rule 5250(c)(1) for continued listing. In the letters, Nasdaq requested that Misonix submit a plan to regain compliance with the Listing Rules by November 14, 2016.

On November 14, 2016, Misonix submitted to Nasdaq a plan to regain compliance with the Rules. After reviewing Misonix's plan to regain compliance, Nasdaq granted an exception to enable the Company to regain compliance with the Rules. Under the terms of the exception, Misonix must file the 10-K and 10-Q on or before March 13, 2017. In the event that Misonix does not satisfy the terms set forth in the extension, Nasdaq will provide written notification that Misonix's common stock will be delisted. At that time, Misonix may appeal Nasdaq's determination for a panel review.

At this time, this extension has no effect on the listing of the Common Stock on The Nasdaq Global Market.

The following table sets forth the high and low sales prices for the Common Stock during the periods indicated as reported by the Nasdaq Global Market:

	High	Low
Fiscal 2016:		
First Quarter	$12.00	$8.20
Second Quarter	11.99	8.41

Third Quarter	9.41	5.64
Fourth Quarter	6.25	3.83

	High	Low
Fiscal 2015:		
First Quarter	$13.49	$6.01
Second Quarter	14.90	8.89
Third Quarter	14.50	10.78
Fourth Quarter	13.90	9.50

As of February 1, 2017, the Company had 9,008,354 shares of Common Stock outstanding and 75 shareholders of record. This amount does not take into account shareholders whose shares are held in "street name" by brokerage houses or other intermediaries.

The Company has not paid any cash dividends since its inception. The Company does not intend to pay any cash dividends in the foreseeable future, but intends to retain all earnings, if any, for use in its business operations.

Share Performance Graph

The following graph compares the cumulative total return on the Company's Common Stock during the last five fiscal years with the NASDAQ Total U.S. and Foreign Return Index and the NASDAQ Medical Devices, Instruments and Supplies Index during the same period. The graph shows the value, at the end of each of the last five fiscal years, of $100 invested in the Common Stock or the indices on June 30, 2011. The graph depicts the change in value of the Company's Common Stock relative to the noted indices as of the end of each fiscal year and not for any interim period. Historical stock price performance is not necessarily indicative of future stock price performance.

	2011	2012	2013	2014	2015	2016
MISONIX, INC.	100	93	203	269	378	206
NASDAQ Composite Total Return	100	107	126	165	189	186
NASDAQ Medical Equipment Index	100	102	121	158	186	217

Item 6. Selected Financial Data.

The following selected consolidated financial data should be read in conjunction with Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing in Item 8 "Financial Statements and Supplementary Data" of the 10-K.

The consolidated statements of income data for the years ended June 30, 2014, 2015 and 2016 and the consolidated balance sheet data as of June 30, 2015 and 2016 are derived from our audited consolidated financial statements appearing in Item 8 of the 10-K. The consolidated statements of income data for the years ended June 30, 2012 and 2013 and the consolidated balance sheet data as of June 30, 2012, 2013 and 2014 are derived from our audited consolidated financial statements that are not included in the 10-K. The historical results are not necessarily indicative of the results to be expected in any future period.

Selected income statement data:

	For the Year Ended June 30,				
	2016	2015	2014	2013	2012
Net sales	$23,113,194	$22,204,578	$17,060,435	$14,827,226	$15,678,000
Net (loss)/income from continuing operations	(1,329,077)	5,304,056	1,126,580	(2,846,747)	(608,765)
Net (loss)/income per share from continuing operations - Basic	$(0.17)	$0.70	$0.15	$(0.40)	$(0.09)
Net (loss)/income per share from continuing operations - Diluted	$(0.17)	$0.66	$0.15	$(0.40)	$(0.09)

Selected balance sheet data:

	June 30,				
	2016	2015	2014	2013	2012
Total assets	$27,732,371	$26,454,248	$19,527,869	$17,359,927	$18,312,837
Total long term liabilities	$31,685	$20,395	$67,932	$96,745	$140,143
Total stockholders' equity	$24,401,290	$23,754,345	$16,352,364	$13,777,220	$15,590,067

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

Misonix designs, manufactures, develops and markets therapeutic ultrasonic devices. These products are used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, orthopedic surgery, plastic surgery, and wound and burn care. In the United States, the Company sells its products through a network of commissioned agents assisted by company personnel. Outside of the United States, the Company generally sells to distributors who then resell the product to hospitals.

In the United States, the Company is taking a more aggressive approach to taking market share, expanding the market and increasing its share of recurring disposable revenue by using a consignment model, whereby the Company will consign the equipment (which is defined as a generator, hand units and accessories) (the “Equipment”) and sell to customers higher margin disposable, single use items (the “Consumables”) on a recurring basis. Title remains with the Company with respect to consigned Equipment, which is depreciated and charged to selling expenses over a five year

period. Outside of the United States, the Company has principally not yet adopted a consignment model. The Company’s overall goal is to increase the utilization rate of Equipment which will increase the total number of procedures and maximize the sale of Consumables to our customers, with the goal of becoming the standard of care in the various segments we focus on.

Results of Operations

The following discussion and analysis provides information which the Company's management believes is relevant to an assessment and understanding of the Company's results of operations and financial condition. This discussion should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere herein. Unless otherwise specified, this discussion relates solely to the Company's continuing operations.

All of the Company's sales have been derived from the sale of medical device products, which include manufacture and distribution of ultrasonic medical device products. Our sales by category for the three years ended June 30, 2016 are as follows:

	For the Year Ended June 30,			Net Change % Year Ended June 30,	
	2016	2015	2014	2016	2015
Total					
Consumables	$16,091,651	$12,833,377	$8,579,137	25.4 %	49.6 %
Equipment	7,021,543	9,371,201	8,481,298	-25.1 %	10.5 %
Total	$23,113,194	$22,204,578	$17,060,435	4.1 %	30.2 %
Domestic:					
Consumables	$11,277,449	$8,449,215	$5,042,496	33.5 %	67.6 %
Equipment	1,809,357	2,348,705	3,142,972	-23.0 %	-25.3 %
Total	$13,086,806	$10,797,920	$8,185,468	21.2 %	31.9 %
International:					
Consumables	$4,814,202	$4,384,162	$3,536,641	9.8 %	24.0 %
Equipment	5,212,186	7,022,496	5,338,326	-25.8 %	31.5 %
Total	$10,026,388	$11,406,658	$8,874,967	-12.1 %	28.5 %

Fiscal years ended June 30, 2016 and 2015

Net sales

Net sales increased $908,616, or 4.1%, to $23,113,194 in fiscal 2016 from $22,204,578 in fiscal 2015 in part due to stronger demand for the Company’s products domestically offset by weaker international Equipment sales. Consumables revenue increased by 25.4% to $16,091,651 for the year ended June 30, 2016 compared with $12,883,377 in the prior year. Equipment sales declined by 25.1% to $7,021,543 compared with $9,371,201 in the prior year. The decline resulted from weaker international sales, principally in China, where the Company ceased shipments in the fourth quarter of fiscal 2016.

Gross profit

Gross profit was 67.1% in fiscal 2016, about the same as in fiscal 2015, which was 67.2%.

Selling expenses

Selling expenses increased $3,233,390 to $12,296,085 in fiscal 2016 from $9,062,695 in fiscal 2015. The Company continues to invest in sales and marketing in order to gain market share. The Company's strategy to leverage its existing distributor network with product specialists domestically resulted in part in domestic sales growing by 21.2% during the current fiscal year. The expense increase is related to higher salary expenses of $1,140,737 due to increased head count, higher commissions of $798,432 from sales programs to increase the number of consigned units domestically, higher travel expenses of $349,701, higher advertising expenses of $344,322, higher depreciation expenses of $318,472 due to the increased consigned units, higher employee benefit expenses of $154,175 due to increased head count, higher training expenses of $57,733, higher freight-out expenses of $54,906 and higher other expenses of $14,912.

General and administrative expenses

General and administrative expenses increased $1,381,287 to $7,364,910 in fiscal 2016 from $5,983,623 in fiscal 2015. The increase is due to higher non-cash compensation expenses of $522,393 due to the issuance of stock options, higher accounting expenses of $497,932 relating in part to the Company becoming an accelerated filer, higher insurance expenses of $175,584, higher salary expenses of $147,119 and higher depreciation expenses of $39,937.

Research and development expenses

Research and development expenses increased $77,424 to $1,670,347 in fiscal 2016 from $1,592,923 in fiscal 2015. The increase is due generally to higher product development expenses.

Other income

Other income decreased $307,403 to $3,926,960 in fiscal 2016 from $4,234,363 in fiscal 2015. The decrease is related to lower royalty income from MMIT. This royalty agreement expires in August 2017.

Income taxes

In fiscal 2016 the income tax benefit for continuing operations had an effective tax rate of 30.1% as compared to an effective rate of 110.5% in fiscal 2015. Prior to June 30, 2014 and through March 31, 2015, the Company had a full valuation allowance recorded against deferred tax assets. The primary factors affecting the fiscal 2016 effective tax rate were non-deductible expenses, deferred tax adjustments and state income taxes. As of the year ended June 30, 2015, the Company reduced the valuation allowance by $5,503,417. The change in the valuation allowance includes a $1,499,297 write-off of deferred tax assets against its corresponding valuation allowance. The write-off primarily pertains to a loss in tax benefit for net operating losses subject to limitation under federal tax law that preclude its utilization. In addition, during the fourth quarter of fiscal 2015, based on our consideration of all available positive and negative evidence including achieving cumulative profitable operating performance over the past three years and our positive outlook for taxable income in the future, the Company reevaluated its deferred tax asset. Based upon the guidance under ASC 740, we concluded that it was more likely than not that the Company would realize the benefit of such deferred tax assets. The portion of the valuation allowance release attributable to income in future years resulted in the recognition of a tax benefit of $2,892,000 in continuing operations in the fourth quarter of fiscal 2015. The deferred tax asset will be realized against future income tax expense that would be payable in the absence of the net operating loss carryforwards. The Company still maintains a full valuation allowance on all foreign net operating losses in the amount of $628,730.

Fiscal years ended June 30, 2015 and 2014

Net sales

Net sales increased $5,144,143, or 30.2%, to $22,204,578 in fiscal 2015 from $17,060,435 in fiscal 2014, in part due to stronger demand for the Company’s products, particularly Consumables. Consumables revenue increased by 49.6% to $12,833,377 for the year ended June 30, 2015 compared with $8,579,137 in the prior year, principally from strong domestic sales. Equipment revenue increased by 10.5% to $9,371,201, compared with $8,481,298. The increase was the result of stronger international sales.

Gross profit

Gross profit increased to 67.2% in fiscal 2015 from 65.2% in fiscal 2014. The increase is primarily related to higher sales volume as well as a favorable product mix of higher margin product deliveries in fiscal 2015. The higher sales volume resulted in higher coverage of fixed expenses resulting in higher margins.

Selling expenses

Selling expenses increased $1,789,969 to $9,062,695 in fiscal 2015 from $7,272,726 in fiscal 2014. The increase is related to higher sales commissions of $560,371, higher salary expenses of $484,083 due to increased head count,

higher depreciation expense of $233,833 due the increase in the number of demo units used for consignments in the field, higher travel expense of $218,143, higher consulting expenses of $188,475 and higher employee welfare and office expense of $92,426.

General and administrative expenses

General and administrative expenses increased $1,292,568 to $5,983,623 in fiscal 2015 from $4,691,055 in fiscal 2014. The increase is due to higher consulting expenses of $616,541 mainly as a result of a onetime expense related to the upgrade of the Company's information and technology systems, higher non-cash compensation from the issuance of stock options of $410,365, higher investor relations expenses of $67,105, higher office expenses of $57,952, higher insurance expenses of $45,964, higher bonus and bank fee expenses of $55,264 and higher employment fees of $35,163.

Research and development expenses

Research and development expenses decreased $118,828 to $1,592,923 for fiscal 2015 from $1,711,751 for fiscal 2014. The decrease is due to lower product development material expenses of $70,035, lower consulting expenses of $48,151 and lower other expenses of $642.

Other income

Other income increased $528,189 to $4,234,363 in fiscal 2015 from $3,706,174 in fiscal 2014. The increase is related to higher royalty income from MMIT.

Income taxes

In fiscal 2015 and 2014 the income tax benefit for continuing operations had an effective tax rate of 110.5% as compared to income tax expense with an effective rate of .2% in fiscal 2014. Prior to June 30, 2014 and through March 31, 2015, the Company had a full valuation allowance recorded against deferred tax assets. As of the year ended June 30, 2015, the Company reduced the valuation allowance by $5,503,417. The change in the valuation allowance includes a $1,499,297 write-off of deferred tax assets against its corresponding valuation allowance. The write-off primarily pertains to a loss in tax benefit for net operating losses subject to limitation under federal tax law that preclude its utilization. In addition, during the fourth quarter of fiscal 2015, based on our consideration of all available positive and negative evidence including achieving cumulative profitable operating performance over the past three years and our positive outlook for taxable income in the future, the Company reevaluated its deferred tax asset. Based upon the guidance under ASC 740, we concluded that it was more likely than not that the Company would realize the benefit of such deferred tax assets. The portion of the valuation allowance release attributable to income in future years resulted in the recognition of a tax benefit of $2,892,000 in continuing operations in the fourth quarter of fiscal 2015. The deferred tax asset will be realized against future income tax expense that would be payable in the absence of the net operating loss carryforwards. The Company still maintains a full valuation allowance on all foreign net operating losses in the amount of $628,730.

Discontinued operations

The following represents the results of the Laboratory and Forensic Safety Products business along with legal and other expenses associated with Labcaire Systems Limited and Misonix HIFU Technologies Limited which are included in discontinued operations:

	For the years ended June 30,		
	2016	2015	2014
Revenues	$-	$18,242	$19,901
Income from discontinued operations, before tax	$-	$18,242	$19,901
Gain on sale of discontinued operations	250,000	250,000	250,000
Income tax benefit/(expense)	(93,069)	(1,127)	(3,182)
Net income from discontinued operations, net of tax	$156,931	$267,115	$266,719

See Note 1 of the Notes to Consolidated Financial Statements for further discussion of the nature of discontinued operations.

Liquidity and Capital Resources

Working capital at June 30, 2016 and 2015 was $15,982,000 and $18,289,000, respectively. For the fiscal year ended June 30, 2016, cash used in operations totaled $316,240, mainly due to the higher net loss, partially offset by lower accounts receivable. For the fiscal year ended June 30, 2016, cash used in investing activities totaled $604,560, primarily consisting of the purchase of property, plant and equipment along with filing for additional patents. For the fiscal year ended June 30, 2016, cash provided by financing activities was $189,447. Cash provided by discontinued operations was $156,931.

The Company’s cash balance at December 31, 2016 was $12,766,120.

On October 25, 2016, the Company sold 761,469 shares of Common Stock in a private placement to Stavros G. Vizirgianakis, a director of the Company and its current Chief Executive Officer, at a price per share of $5.253, representing total cash proceeds to the Company of approximately $4.0 million. As of June 30, 2016, the Company had a cash balance of $9,049,327 and believes it has sufficient cash to finance operations for at least the next 12 months.

The Company maintains cash balances at various financial institutions. At June 30, 2016, these financial institutions held cash that was approximately $8,798,987 in excess of amounts insured by the Federal Deposit Insurance Corporation.

Relating to the FCPA matter described in Part I – Item 3 above, the Company has incurred approximately $1.5 million in investigative costs and is expected to incur additional costs until the matter is fully resolved. Further, the Company could be subject to fines or penalties related to potential violations of the FCPA.

The Company has been receiving an annual MMIT royalty from MMIT which has averaged $3.7 million per year over the last three fiscal years. This royalty will end in August 2017.

Commitments

The Company has commitments under operating leases that will be funded from operating sources. At June 30, 2016, the Company's contractual cash obligations and commitments relating to operating leases are as follows:

Commitment	Less than 1 year	1-3 years	4-5 years	After 5 years	Total
Operating leases	$343,949	$383,263	$ 8,569	$ -	$735,781
Purchase commitments	2,507,125	-	-	-	2,507,125
	$2,851,074	$383,263	$ 8,569	$ -	$3,242,906

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to the Company.

Other

In the opinion of management, inflation has not had a material effect on the operations of the Company.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities, and the reported amounts of revenues and expenses. Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include net realizable value of inventories, valuation of intangible assets including amortization periods for acquired intangible assets, estimates of projected cash flows and discount rates used to value intangible assets and test goodwill and intangible assets for impairment, computation of valuation allowances recorded against deferred tax assets, and valuation of stock-based compensation. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the current circumstances. Actual results could differ from these estimates.

We believe that the following accounting policies, which form the basis for developing these estimates, are those that are most critical to the presentation of our consolidated financial statements and require the more difficult subjective and complex judgments:

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost (determined by the first-in, first-out method) or market. At each balance sheet date, we evaluate ending inventories for excess quantities and obsolescence. Our evaluation includes an analysis of historical sales levels by product, projections of future demand by product, the risk of technological or competitive obsolescence for our products, general market conditions, and the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which we do not have excess quantities in inventory. To the extent that we determine there are excess or obsolete quantities or quantities on hand, we adjust their carrying value to estimated net realizable value. If future demand or market conditions are lower than our projections, or if we are unable to rework excess or obsolete quantities into other products, we may record further adjustments to the carrying value of inventory through a charge to cost of product revenues in the period the revision is made.

Goodwill

The excess of the cost over the fair value of net assets of acquired businesses is recorded as goodwill. Goodwill is not subject to amortization, but is reviewed for impairment at the reporting unit level annually, or more frequently if impairment indicators arise. Our assessment of the recoverability of goodwill is based upon a comparison of the carrying value of goodwill with its estimated fair value and the value of the Company at the measurement date.

Application of these impairment tests requires significant judgments, including estimation of cash flows, which is dependent on internal forecasts, estimation of the long term rate of growth for our business, the useful lives over which cash flows will occur and determination of our weighted average cost of capital. We primarily utilize a discontinued cash flow model in determining the fair value which consists of Level 3 inputs. Changes in the projected cash flows and discount rate estimates and assumptions underlying the valuation of goodwill could materially affect the determination of fair value at acquisition or during subsequent periods when tested for impairment.

Income Taxes

The Company assesses whether a valuation allowance should be established against its deferred tax assets based on consideration of all available evidence, both positive and negative, using a more likely than not standard. This assessment considers, among other matters, the nature, frequency and severity of recent losses; a forecast of future profitability; the duration of statutory carryback and carryforward periods; the Company's experience with tax attributes expiring unused; and tax planning alternatives. The likelihood that the deferred tax asset balance will be recovered from future taxable income is assessed at least quarterly, and the valuation allowance, if any, is adjusted

accordingly.

Loss Contingencies

We are subject to claims and lawsuits in the ordinary course of our business, including claims by employees or former employees, with respect to our products and involving commercial disputes, or shareholder actions. We accrue for loss contingencies when it is deemed probable that a loss has been incurred and that loss is estimable. The amounts accrued are based on the full amount of the estimated loss before considering insurance proceeds, if applicable, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. Our financial statements do not reflect any material amounts related to possible unfavorable outcomes of claims and lawsuits to which we are currently a party because we currently believe that such claims and lawsuits are not expected, individually or in the aggregate, to result in a material adverse effect on our financial condition. However, it is possible that these contingencies could materially affect our results of operations, financial position and cash flows in a particular period if we change our assessment of the likely outcome of these matters. Relating to the FCPA matter described in Part I – Item 3 above, the Company has incurred approximately $1.5 million in investigative costs and is expected to incur additional costs until the matter is fully resolved. Further, the Company could be subject to fines or penalties related to potential violations of the FCPA.

Stock-Based Compensation

We recognize compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using the Black-Scholes option valuation model, and is being expensed in the financial statements over the service period and is recorded in general and administrative expenses. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield.

Recently Issued and Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued guidance on revenue from contracts with customers. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved, in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. This guidance permits the use of either the retrospective or cumulative effect transition method and is effective for the Company beginning in 2019; early adoption is permitted beginning in 2018. We have not yet selected a transition method and are currently evaluating the impact of the guidance on the Company's financial condition, results of operations and related disclosures. The FASB has also issued the following additional guidance clarifying certain issues on revenue from contracts with customers: Revenue from Contracts with Customers - Narrow-Scope Improvements and Practical Expedients and Revenue from Contracts with Customers - Identifying Performance Obligations and Licensing. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its financial statements.

In August 2014, the FASB issued guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and related footnote disclosures. Management will be required to evaluate, at each reporting period, whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. This guidance is effective prospectively for annual and interim reporting periods beginning in 2017; implementation of this guidance is not expected to have a material effect on the Company’s financial condition or results of operations.

In July 2015, the FASB issued ASU “Inventory (Topic 330).” The amendments in this update are effective for fiscal years beginning after December 2016. We are in the early stages of determining the impact of this standard on our financial statements.

In November 2015, the FASB issued ASU 2015-17 “Balance Sheet Classification of Deferred Taxes (Topic740)”. The amendments in this ASU require deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments eliminate the guidance in Topic 740 that requires an entity to separate deferred tax liabilities and assets into a current amount and a noncurrent amount in a classified statement of financial position. The Company adopted ASU 2015-17 as of March 31, 2016 on a prospective basis in order to simplify the balance sheet classification of deferred taxes. Accordingly, the balance sheet for the period ended June 30, 2015 has been shown as previously reported.

In February 2016, the FASB issued guidance on lease accounting requiring lessees to recognize a right-of-use asset and a lease liability for long-term leases. The liability will be equal to the present value of lease payments. This guidance must be applied using a modified retrospective transition approach to all annual and interim periods presented and is effective for the Company beginning in fiscal 2019. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its financial statements.

In March 2016, the FASB issued guidance on simplifying several aspects of accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance requires a mix of prospective, modified retrospective, and retrospective transition to all annual and interim periods presented and is effective for the Company beginning in fiscal 2018. We are in the early stages of determining the impact of this standard on our financial statements.

In August 2016, the FASB issued guidance on the Statement of Cash Flows Classification of certain cash receipts and cash payments (a consensus of the Emerging Issues Task Force). This guidance addresses the following eight specific cash flow issues: Debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (including bank-owned life insurance policies); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. This guidance will be effective for the Company beginning in fiscal 2019. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its financial statements.

There are no other recently issued accounting pronouncements that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

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

Market Risk:

The principal market risks (i.e., the risk of loss arising from adverse changes in market rates and prices) to which the Company is exposed are interest rates on cash and certain items in inventory.

Item 8. Financial Statements and Supplemental Data.

The Company’s report of independent registered public accounting firm and consolidated financial statements listed in the accompanying index is filed as part of this Annual Report. See “Index to Consolidated Financial Statements” on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to provide reasonable assurance that information required to be disclosed in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

All internal control systems, no matter how well designed and tested, have inherent limitations, including, among other things, the possibility of human error, circumvention or disregard. Therefore, even those systems of internal control that have been determined to be effective can provide only reasonable assurance that the objectives of the control system are met and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As described in “Item 3 – Legal Proceedings” in this 10-K, in April 2016, the Company’s management informed the Board of violations of Company policies and procedures and possible violations of laws and regulations, involving Michael A. McManus, the Company’s former President and Chief Executive Officer, and other Company personnel. Subsequently, in mid-May 2016, the Audit Committee of the Board of Directors initiated the Investigation of these matters. Special external counsel was retained and conducted the investigation with the assistance of an advisory firm with forensic accounting expertise. Mr. McManus’ employment with the Company ceased on September 2, 2016.

The Investigation resulted in the Company notifying the SEC and DOJ about possible violations of the FCPA and other internal controls matters. These possible violations of laws included knowledge of certain business practices of the independent Chinese entity that distributes the Company’s products in China, which practices raised questions under the FCPA.

The Investigation did not identify any financial loss to the Company and did not identify any material misstatements in the Company’s financial statements. However, as a result of the Company’s Investigation and related activities, it has incurred approximately $1.5 million of professional fees as of December 31, 2016 and has terminated the agreement with its former distributor in China, which was the Company’s largest customer during the prior three fiscal years. In addition, the Company could be subject to disgorgement, fines or penalties related to potential violations of the FCPA as described in “Item 3 – Legal Proceedings,” above.

In connection with the Investigation, the Company carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of June 30, 2016. Due to the material weaknesses in internal control over financial reporting as described below in “Management’s Report on Internal Control over Financial Reporting”, our current CEO and Interim CFO have concluded that our disclosure controls and procedures were not effective, and were not operating at a reasonable assurance level, as of June 30, 2016.

Management’s Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining effective internal control over financial reporting and for assessing the effectiveness of internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to a process designed by, or under the supervision of, our CEO and our CFO and effected by our Board, management and other personnel, 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, and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and members of our Board; and

- 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of June 30, 2016, based on the criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon this evaluation, management has determined, because of the findings from the Investigation, and the Company's inability to rely on certain personnel, processes and internal controls, that a material weakness existed at June 30, 2016, as described below. In light of such material weakness, management has concluded that the Company's internal control over financial reporting was ineffective as of June 30, 2016.

The Company did not have an effective control environment, risk assessment process, information and communication process and monitoring activities. These matters related to ineffective ethical governance, ineffective governance controls, and ineffectively implemented policies and procedures. The aggregation of issues identified within each of these areas resulted in the conclusion that a material weakness existed with respect to the "tone at the top" and effectiveness of governance within the Company. Specifically:

- The Company failed to establish a tone at the top that demonstrated its commitment to integrity and ethical values.

- The Company lacked effective controls and procedures to ensure that all members of management and Board members report to the full Board all possible illegal acts and violations of Company policy.

- The Company lacked effective procedures and controls to ensure that all reimbursement requests are handled in a manner consistent with the Board's authorizations and the Company's policies and procedures.

- The Company did not have effective information and communication and monitoring controls, including a robust whistleblower process, relating to the timely identification and communication of issues among financial reporting personnel, management, the Board, and the independent registered public accounting firm to enable appropriate analysis, financial reporting, and disclosure of such transactions.

The Company did not have effective information and communication and monitoring controls, including a robust whistleblower process, to ensure the timely identification and communication of issues to financial reporting

personnel, management, and the Board, to enable appropriate financial reporting and disclosure of such transactions.

In addition, the Company did not properly supervise the preparation and review the calculation of its income tax provision and deferred tax asset. While this control deficiency did not result in a material misstatement of the Company's financial statements, it could have resulted in misstatements of the aforementioned accounts and disclosures that would not be prevented or detected in a timely manner. Accordingly, our management concluded that this control deficiency also constitutes a material weakness.

The identified control deficiencies did not result in any material misstatements in the Company's financial statements. However, these control deficiencies created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis. Accordingly, we concluded that the control deficiencies represented material weaknesses in the Company's internal control over financial reporting and our internal control over financial reporting was not effective as of June 30, 2016.

The independent registered public accounting firm, Grant Thornton LLP, has expressed an adverse report on the operating effectiveness of our internal control over financial reporting as of June 30, 2016. Grant Thornton LLP's report appears in Item 8 of this 10-K.

Remediation of Material Weakness

The Company continues to work to strengthen our internal control over financial reporting. We are committed to ensuring that such controls are designed and operating effectively. Our Board and management take internal control over financial reporting and the integrity of the Company's financial statements seriously and believe that the remediation steps described below, including with respect to personnel changes, were and are essential steps to establishing and maintaining strong and effective internal control over financial reporting and addressing the tone at the top concerns that contributed to the material weakness identified. None of these remediation steps had taken place as of June 30, 2016. The following actions and plans will be or have been implemented during the fiscal 2017 year:

- The Board replaced Mr. McManus effective September 2, 2016 with our then interim and now current CEO, Stavros G. Vizirgianakis. In addition, on September 13, 2016, the Board appointed Joseph P. Dwyer as the Company's interim CFO, reporting to the Company's new CEO and the Audit Committee of the Board. On that date, Richard A. Zaremba ceased serving as the Company's Senior Vice President and CFO and was appointed Senior Vice President, Finance, while remaining as the Company's Secretary and Treasurer.

- In November 2016, the Company hired an Interim Chief Compliance Officer who reports directly and regularly to the CEO and the Chairman of the Audit Committee. The Interim Chief Compliance Officer is implementing an improved documentary framework, focusing initially on FCPA compliance and working with the Company's sales and marketing personnel.

- The Board, as recommended by the Interim Chief Compliance Officer, reconstituted the Company's internal compliance committee to include the entire senior management team, with the Chief Compliance Officer as Chair and the sales and marketing officers as non-voting members. This action was designed in part to ensure that all members of senior management report all possible illegal acts.

- The Company reconstituted the membership of its Board committees. T. Guy Minetti, former Chairman of our Audit Committee, resigned from the Board on December 15, 2016.

- The Board reviewed and updated its Committee charters to provide, among other things, a more robust and structured governance process.

- The Company updated its Code of Conduct and Ethics and implemented a toll-free whistleblower hotline that is reported directly to the Chairman of the Audit Committee. In addition, the Company has increased communication and will increase training to employees regarding the ethical values of the Company and the requirement to comply with laws, rules, regulations, and Company policies, including the Code of Conduct and Ethics, and the importance of accurate and transparent financial reporting.

- Under the supervision of the Board, the Company will emphasize to key leadership the importance of setting appropriate tone at the top and of appropriate behavior with respect to accurate financial reporting, compliance with laws, and adherence to the Company's internal control over financial reporting framework and accounting policies.

- The Company terminated the agreement with its former independent distributor of its products in China.

- The Company is amending distribution agreements with its international distributors to add more fulsome provisions regarding compliance with laws, including compliance with the FCPA and other applicable anti-bribery provisions.

- The Company is instituting a more robust screening process for its independent distributors with respect to legal compliance, including compliance with the FCPA and other applicable anti-bribery provisions.

- The Company is implementing a regularly recurring risk assessment process focused on identifying and analyzing risks of financial misstatement due to error and/or fraud, including management override of controls.

- The Company is updating its policies and procedures to ensure the proper processing of transactions with senior executives, and to enhance the review and approval for these types of transactions and ensure their proper disclosure, and will train relevant employees on such updated policies.

- We have engaged a third-party expert consulting firm specializing in tax and technical accounting and financial reporting issues to assist our management with the review of our tax provisions and the accounting treatment and the financial reporting and disclosure of complex and non-recurring transactions.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth fiscal quarter ended June 30, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As noted above, subsequent to June 30, 2016, the Company began the process of enhancing existing controls and designing and implementing additional controls and procedures in response to the material weaknesses.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers of the Registrant and Corporate Governance.

The Company currently has five Directors (the "Board"). Their term expires at the next Annual Meeting of Shareholders. The following table contains information regarding all Directors and executive officers of the Company as of December 31, 2016:

Name	Age	Principal Occupation	Director Since
John W. Gildea	73	Director	2004