INTRICON CORP
Form 10-K
March 11, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

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 1-5005

INTRICON CORPORATION

(Exact name of registrant as specified in its charter)

Pennsylvania (State or other jurisdiction of incorporation or organization)	23-1069060 (I.R.S. Employer Identification No.)

1260 Red Fox Road Arden Hills, Minnesota (Address of principal executive offices)	55112 (Zip Code)

Registrant's telephone number, including area code (651) 636-9770

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

Title of each class	Name of each exchange on which registered
Common Shares, $1 par value per share	The 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 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 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 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 No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer		Accelerated filer
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 by rule 12b-2 of the Act). Yes No

The aggregate market value of the voting common shares held by non-affiliates of the registrant on June 30, 2015 was $36,586,092. Common shares held by each officer and director and by each person who owns 10% or more of the outstanding common shares have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common shares on February 23, 2016 was 5,981,756.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive proxy statement for the 2016 annual meeting of shareholders are incorporated by reference into Part III of this report; provided, however, that the Audit Committee Report and any other information in such Proxy Statement that is not required to be included in this Annual Report on Form 10-K, shall not be deemed to be incorporated herein or filed for the purposes of the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended.

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PART I

ITEM 1. Business

Company Overview

IntriCon Corporation (together with its subsidiaries referred herein as the “Company”, or “IntriCon”, “we”, “us” or “our”) is an international company engaged in designing, developing, engineering, manufacturing and distributing body-worn devices. The Company serves the body-worn device market by designing, developing, engineering, manufacturing and distributing micro-miniature products, microelectronics, micro-mechanical assemblies, complete assemblies and software solutions, primarily for the emerging value hearing health market, the medical bio-telemetry market and the professional audio communication market. The Company, headquartered in Arden Hills, Minnesota, has facilities in Minnesota, California, Singapore, Indonesia, the United Kingdom and Germany, and operates through subsidiaries. The Company is a Pennsylvania corporation formed in 1930, and has gone through several transformations since its formation. The Company’s core business of body-worn devices was established in 1993 through the acquisition of Resistance Technologies Inc., now known as IntriCon, Inc. The majority of IntriCon’s current management came to the Company with the Resistance Technologies Inc. acquisition, including IntriCon’s President and CEO, who was a co-founder of Resistance Technologies Inc.

Currently, the Company operates in one operating segment, the body-worn device segment. On June 13, 2013, the Company announced a global restructuring plan to accelerate future growth and reduce costs. As part of the restructuring, the Company sold its security and certain microphone and receiver operations on January 27, 2014 to Sierra Peaks Corporation. For all periods presented, the Company classified these businesses as discontinued operations, and, accordingly, has reclassified historical financial data presented herein.

Information contained in this Annual Report on Form 10-K and expressed in U.S. dollars or number of shares are presented in thousands (000s), except for per share data and as otherwise noted.

Business Highlights

Major Events in 2015

The Company reported its strongest financial results in over a decade, surpassing 2014 results, including its strongest revenue and margin since the rebranding of the Company in 2005.

On November 3, 2015, the Company acquired the assets of PC Werth, a leading supplier of hearing healthcare products and equipment to the United Kingdom's National Health Service (NHS). The NHS is the largest purchaser of hearing aids in the world, supplying an estimated 1.2 million hearing aids annually.

On November 2nd, 2015, the company launched JD Edwards EnterpriseOne platform, a $2,400 investment in an integrated applications suite of comprehensive enterprise resource planning (ERP) software, to further support its global manufacturing and distribution footprint.

On September 14, 2015, the Company and The Academy of Doctors of Audiology (ADA), announced a joint venture to provide hearing instruments and educational resources that offer unprecedented value for audiologists and their patients.

On March 31, 2015, the Company and its domestic subsidiaries entered into a Seventh Amendment to the Loan and Security Agreement and Waiver with The PrivateBank and Trust Company, which among other things extended the maturity date of the term loan and revolving credit facility to February 28, 2019 (See Note 8 to the Company's consolidated financial statements included herein).

Major Events in 2014

On December 4, 2014, the Company announced an exclusive distribution agreement with PC Werth in the United Kingdom. PC Werth, through its partnership with IntriCon, has been appointed as one of the main suppliers to the NHS Supply Chain's National Framework.

On January 27, 2014, the Company sold its remaining security and certain microphone and receiver operations, which marked the final milestone in the global strategic restructuring plan announced in 2013.

Major Events in 2013

On June 13, 2013, the Company announced a global strategic restructuring plan designed to accelerate the Company's future growth by focusing resources on the highest potential growth areas and reduce costs. As part of this plan, the Company reduced investment in certain non-core professional audio communications product lines; transferred specific product lines from Singapore to the Company's lower-cost manufacturing facility in Batam, Indonesia; reduced its global administrative and support workforce; transferred the medical coil operations from the Company's Maine facility to Minnesota to better leverage existing manufacturing capacity, added experienced professionals in value hearing health; and focused more resources in medical biotelemetry. During the 2013 third quarter, the Company's customer, Medtronic, received Food and Drug Administration (FDA) approval for their MiniMed 530G insulin pump. Medical market sales strengthened in the 2013 fourth quarter as Medtronic ramped for its launch of the MiniMed 530G.

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Market Overview:

IntriCon serves the body-worn device market by designing, developing, engineering, manufacturing and distributing micro-miniature products, microelectronics, micro-mechanical assemblies, complete assemblies and software solutions, primarily for the emerging value hearing health market, the medical bio-telemetry market and the professional audio communication market. Revenue from the medical bio-telemetry and value hearing health markets is reported on the respective medical and hearing health lines in the discussion of our results of operations in “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Note 18 “Revenue by Market” to the Company’s consolidated condensed financial statements included herein.

Value Hearing Health Market

The Company believes the value hearing health (VHH) market offers significant growth opportunities. In the United States alone, there are approximately 48 million adults that report some degree of hearing loss. In adults the most common cause of hearing loss is aging and noise. In fact, by the age of 65 year old, one out of three people have hearing loss. The hearing impaired population is expected to grow significantly over the next decade due to an aging population and more frequent exposure to loud sounds that can cause noise-induced hearing loss. It is estimated that hearing aids can help more than 90 percent of people with hearing loss, however the current market penetration into the U.S. hearing impaired population is approximately 20 percent, a percentage that has remained essentially unchanged for the last four decades. In early January, the U.S. Food and Drug Administration (FDA) weighed in on low hearing aid penetration rates with an announcement that highlighted statistics from the National Institute on Deafness and Other Communication Disorders. They found that 37.5 million U.S. adults aged 18 and older report some form of hearing loss. However, only 30 percent of adults over 70, and 16 percent of those aged 20 to 69 who could benefit from wearing hearing aids, have ever used them. Based on these statistics, the FDA has reopened the public comment period on draft guidance related to the agency’s premarket requirements for hearing aids and PSAPs. The FDA’s intent is to consider ways in which regulation can support further penetration into the hearing market.

In October 2015, the President’s Council of Advisors on Science & Technology (PCAST), the group that makes policy recommendations to the President, also addressed the low hearing health market penetration levels IntriCon has long pointed out. PCAST indicated that untreated hearing loss in the United States is a substantial national problem, and supported this assessment with references to the barriers to access. The group recommended revising FDA regulations and changing the current distribution channel, as well as creating new channels to increase the opportunities for consumer choice. A link to both the FDA announcement and the PCAST letter can be found on our website.

We believe the U.S. market penetration is low primarily due to the high costs to purchase a hearing aids, consolidation at the retail level and inconveniences in the distribution channel. These factors have created the opportunity for

alternative care models, such as the value hearing aid (VHA) channel and personal sound amplifier (PSAP) channel. The VHA channel is outcome based focused and requires the best device and software technology, to provide the most efficient, lowest cost solution to the consumer. IntriCon has positioned itself as a leader in these channels through significant, on-going investments in sales and marketing and research and development. The Company is aggressively pursuing prospective partnerships and customers who can benefit from our value proposition and the VHA and PSAP channels.

In the VHA channel, the Company entered into a manufacturing agreement with hi HealthInnovations, a UnitedHealth Group company, to become their supplier of hearing aids. At the beginning of 2012, hi HealthInnovations launched a suite of high-tech, lower-cost hearing devices for their Medicare and Part D participants and later in the year announced they were increasing this offering to the over 26 million people enrolled in their employer-sponsored and individual health benefit plans. In 2012, they have expanded their offering to include a hearing aid discount program for health plans. This program is available nationwide to all health insurers, including employer-sponsored, individual and Medicare plans. The insurance model has been successfully demonstrated internationally, where several countries providing a full insurance program are serving 40 to 70 percent of the hearing impaired population. Further, research in the U.S. has shown a fully insured model will encourage an individual to seek treatment at an earlier stage of hearing loss, greatly increasing the market size and penetration. The Company also has various international VHA initiatives. In 2014, the Company entered into an exclusive distribution agreement with PC Werth in the United Kingdom. PC Werth, through its partnership with IntriCon, has been appointed as one of the main suppliers to the National Health Service (NHS) Supply Chain’s National Framework. The NHS is widely seen as the most efficient hearing aid delivery system in the world, supplying an estimated 1.4 million hearing aids annually. We believe IntriCon is well positioned to serve their needs, and we’re developing new technologies to further enhance delivery efficiencies and product standards in the future. On November 3, 2015, the Company acquired the assets of PC Werth to gain direct access to the NHS and to have greater control over its efforts to accelerate new market penetration into the United Kingdom. Our integration plan, which will include site relocation, reallocating resources and leveraging corporate infrastructure, is proceeding on schedule and we anticipate these efforts to be complete by the end of the 2016 third quarter.

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We also believe there are niches in the conventional hearing health channel that will embrace our VHA proposition in the United States and Europe. High costs of conventional devices and retail consolidation have constrained the growth potential of the independent audiologist and dispenser. We believe our software and product offering can provide independent audiologists and dispensers the ability to compete with larger retailers, such as Costco, and manufacturer owned retail distributors. In Europe, we recently secured a two-year supply agreement with AudioNova International, one of Europe's leading hearing aid providers, operating more than 1,300 retail stores in 11 countries. Through our new supply agreement, AudioNova will offer hearing devices, manufactured by IntriCon. AudioNova's smartsound brand is based on IntriCon's Audion™ amplifier, and offers technically advanced features at value hearing health price points. AudioNova has begun rollout of the smartsound brand in the Netherlands and intends to expand the program to other targeted European countries in the future. In the third quarter of 2015, we announced a joint venture with The Academy of Doctors of Audiology (ADA) to provide hearing instruments and educational resources to audiologists and their patients. The joint venture will operate under the name earVenture LLC. earVenture was officially launched in November at the ADA conference. We expect that this joint venture will capitalize on our established reputation as a leading provider of high quality, low-cost hearing aids and the ADA's respected position as the only national membership association focused on ownership of the audiology profession through autonomous practice and clinical excellence. To date, more than 400 of the 1,200 ADA members have registered to join the earVenture program and we have delivered initial units. In 2016, earVenture will be rolling-out a comprehensive marketing and sales plan to convert those registered members to consistent customers as well as solicit non-registered ADA members to join the program.

In the past few years the PSAP channel, which includes ear worn devices that provide cost effective sound amplification, has begun to emerge. These sound amplification devices are not regulated by the FDA, as they are not hearing aids and make no claims of compensating for hearing loss. They can be purchased "off-the-shelf" and are not fit or prescribed to meet a specific individual's needs; rather these devices amplify sound and tend to be used in noisy or challenging environments. They have a significantly lower retail price to the consumer than traditional hearing aids.

Additionally, the Company believes there is great potential to market its situational listening devices (SLD's). Similar to the PSAP devices, the Company's SLD's are intended to help people hear in noisy environments, like restaurants and automobiles, and listen to television, music, and direct broadcasts by wireless connection. Such devices are intended to be supplements to conventional hearing aids, which do not handle those situations well. The product line consists of an earpiece, TV transmitter, companion microphone, iPod/iPhone transmitter, and USB transmitter.

Medical Bio-Telemetry

In the medical bio-telemetry market, the Company is focused on sales of bio-telemetry devices for life-critical diagnostic monitoring. Using our nanoDSP and BodyNet™ technology platforms, the Company manufactures microelectronics, micro-mechanical assemblies, high-precision injection-molded plastic components and complete bio-telemetry devices for emerging and leading medical device manufacturers. The medical industry is faced with

pressures to reduce the cost of healthcare. Driven by core technologies, such as the IntriCon Physiolink™ that wirelessly connects patients and care givers in non-traditional ways, IntriCon helps shift the point of care from expensive traditional settings, such as hospitals, to less expensive non-traditional settings like the home. IntriCon currently serves this market by offering medical manufacturers the capabilities to design, develop, manufacture and distribute medical devices that are easier to use, are more miniature, use less power, and are lighter. Increasingly, the medical industry is looking for wireless, low-power capabilities in their devices. We have a strategic relationship with Advanced Medical Electronics Corp. (AME) that allows us to develop new bio-telemetry devices that better connect patients and care givers, providing critical information and feedback. Through the further development of our ULP BodyNet family, we believe the bio-telemetry markets offer significant opportunity.

IntriCon currently has a strong presence in both the diabetes and cardiac diagnostic monitoring bio-telemetry markets. For diabetes, IntriCon has partnered with Medtronic to manufacture their wireless continuous glucose monitors, sensors, and related accessories that measure glucose levels and deliver real-time blood glucose trend information. Our Medtronic business posted record revenue in 2015, led by the MiniLink REAL-Time Transmitter and related accessories sales, which are incorporated in Medtronic’s MiniMed 530G insulin pump and continuous glucose monitoring, or CGM, system. We also manufacture various accessories associated with Medtronic’s CGM system, including the recently announced MiniMed Connect, which links the MiniMed pump and CGM to certain smart devices providing users with a discrete and real-time view of their blood sugar information. In addition to the MiniMed 530G system, the products we manufacture also support Medtronic’s international insulin pump system offerings, such as the recently unveiled MiniMed 640G system. Further, we believe there are opportunities to expand our diabetes product offering with Medtronic as well as move into new markets outside of the diabetes market.

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In the cardiac diagnostic monitoring market, we provide solutions for ambulatory cardiac monitoring. Our first two product platforms, Sirona and Centauri, received FDA 510(k) approval in late 2011. The Sirona platform, which incorporates the PhysioLink technology, is essentially two products in one design: it can be used as an event recorder, a holter monitor or both. This platform is very small, rechargeable, and water spray proof. IntriCon is receiving feedback from its customers about the treatment flexibility and economic benefits of remote patient monitoring. The Company has contracts in place with lead customers for the Sirona platform and anticipates expanding that customer base during 2016.

IntriCon has a suite of medical coils and micro coils that it offers to various original equipment manufacturing (OEM) customers. These products are currently used in pacemaker programming and interventional catheter positioning applications. As part of the global restructuring initiative, the Company is increasing its investment of resources and capital to help expand our customer base and market share.

IntriCon manufactures bubble sensors and flow restrictors that monitor and control the flow of fluid in an intravenous infusion system as well as a family of safety needle products for an OEM customer that utilizes IntriCon’s insert and straight molding capabilities. These products are assembled using full automation, including built-in quality checks within the production lines.

Lastly, IntriCon is targeting other emerging biotelemetry and home care markets, such as sleep apnea, that could benefit from its capabilities to develop devices that are more technologically advanced, smaller and lightweight. To do so, IntriCon is focusing more capital and resources in sales and marketing and research and development to expand its reach to other large medical device and health care companies.

Professional Audio Communications

IntriCon entered the high-quality audio communication device market in 2001, and now has a line of miniature, professional audio headset products used by customers focusing on emergency response needs. The line includes several communication devices that are extremely portable and perform well in noisy or hazardous environments. These products are well suited for applications in the fire, law enforcement, safety, aviation and military markets. In addition, the Company has a line of miniature ear- and head-worn devices used by performers and support staff in the music and stage performance markets. We believe performance in difficult listening environments and wireless operations will continue to improve as these products increasingly include our proprietary nanoDSP, wireless nanoLink and PhysioLink technologies.

For information concerning our net sales, net income and assets, see the consolidated financial statements in Item 8 of this Annual Report on Form 10-K.

Core Technologies Overview:

Our core technologies expertise is focused on three main markets: medical bio-telemetry, value hearing health and professional audio communications. Over the past several years, the Company has increased investments in the continued development of four critical core technologies: Ultra-Low-Power (ULP) Digital Signal Processing (DSP), ULP Wireless, Microminiaturization, and Miniature Transducers. These four core technologies serve as the foundation of current and future product platform development, designed to meet the rising demand for smaller, portable, more advanced devices and the need for greater efficiencies in the delivery models. The continued advancements in this area have allowed the Company to further enhance the mobility and effectiveness of miniature body-worn devices.

ULP DSP

DSP converts real-world analog signals into a digital format. Through our nanoDSP™ technology, IntriCon offers an extensive range of ULP DSP amplifiers for hearing, medical and professional audio applications. Our proprietary nanoDSP incorporates advanced ultra-miniature hardware with sophisticated signal processing algorithms to produce devices that are smaller and more effective.

The Company further expanded its DSP portfolio including improvements to its Reliant CLEAR™ feedback canceller, offering increased added stable gain and faster reaction time. Additionally, the newly developed DSP technologies are utilized in our recently unveiled Audion8™ and Audion16™, our new eight-channel and wide dynamic range compression sixteen-channel hearing aid amplifiers. The amplifiers are feature-rich and are designed to fit a wide array of applications. In addition to multiple compression channels, the amplifiers have a complete set of proven adaptive features which greatly improve the user experience.

ULP Wireless

Wireless connectivity is fast becoming a required technology, and wireless capabilities are especially critical in new body-worn devices. IntriCon's BodyNet™ ULP technology, including the nanoLink™ and PhysioLink™ wireless systems, offers solutions for transmitting the body's activities to caregivers, and wireless audio links for professional communications and surveillance products. Potential BodyNet applications include electrocardiogram (ECG) diagnostics and monitoring, diabetes monitoring, sleep apnea studies and audio streaming for hearing devices.

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IntriCon is in the final stages of commercializing its PhysioLink wireless technology, which will be incorporated into product platforms serving the medical, hearing health and professional audio communication markets. This system is based on 2.4GHz proprietary digital radio protocol in the industrial-scientific-medical (ISM) frequency band and enables audio and data streaming to ear-worn and body-worn applications over distances of up to five meters.

Microminiaturization

IntriCon excels at miniaturizing body-worn devices. We began honing our microminiaturization skills over 30 years ago, supplying components to the hearing health industry. Our core miniaturization technology allows us to make devices for our markets that are one cubic inch and smaller. We also are specialists in devices that run on very low power, as evidenced by our ULP wireless and DSP. Less power means a smaller battery, which enables us to reduce size even further, and develop devices that fit into the palm of one's hand.

Miniature Transducers

IntriCon's advanced transducer technology has been pushing the limits of size and performance for over a decade. Included in our transducer line are our miniature medical coils and micro coils used in pacemaker programming and interventional catheter positioning applications. We believe with the increase of greater interventional care that our coil technology harbors significant value.

Marketing and Competition:

IntriCon intends to focus more capital and resources in marketing and sales to expand its reach into the emerging value hearing health market and large medical device and healthcare companies in the medical bio-telemetry market outlined above. The Company believes this will allow us to advance our technology portfolio, advance new product platforms, strengthen customer relationships and expand our market knowledge.

Currently, IntriCon sells its hearing device products directly to domestic hearing instrument manufacturers, and distributors and partnerships through an internal sales force. Sales of medical and professional audio communications products are also made primarily through an internal sales force. In recent years, a small number of companies have accounted for a substantial portion of the Company's sales.

Internationally, sales representatives employed by IntriCon GmbH ("GmbH"), a wholly owned German subsidiary, solicit sales from European hearing instrument, medical device and professional audio communications manufacturers and suppliers.

In recent years, a small number of customers have accounted for a substantial portion of the Company's sales. In 2015, one customer accounted for approximately 42 percent of the Company's net sales. During 2015, the top five customers accounted for approximately $41,770, or 60 percent, of the Company's net sales. See Note 5 to the consolidated financial statements for a discussion of net sales and long-lived assets by geographic area.

IntriCon believes that it is the largest supplier worldwide of micro-miniature electromechanical components to hearing instrument manufacturers and that its full product line, automated manufacturing process and low cost manufacturing capabilities in Asia, allow it to compete effectively with other manufacturers within this market. In the market of hybrid amplifiers and molded plastic faceplates, hearing instrument manufacturers produce a substantial portion of their internal needs for these components.

IntriCon markets its high performance microphone products to the radio communication and professional audio industries and has several larger competitors who have greater financial resources. IntriCon holds a small market share in the global market for microphone capsules and other related products.

Employees. As of December 31, 2015, the Company had a total of 646 full time equivalent employees, of whom 44 are executive and administrative personnel, 22 are sales personnel, 30 are engineering personnel and 550 are operations personnel. The Company considers its relations with its employees to be satisfactory. None of the Company's employees are represented by a union.

As a supplier of consumer and medical products and parts, IntriCon is subject to claims for personal injuries allegedly caused by its products. The Company maintains what it believes to be adequate insurance coverage.

Research and Development. IntriCon conducts research and development activities primarily to improve its existing products and proprietary technology. The Company is committed to increasing its investment in the research and development of proprietary technologies, such as the ULP nanoDSP and ULP wireless technologies. The Company believes the continued development of key proprietary technologies will be the catalyst for long-term revenues and margin growth. Research and development expenditures were $5,214, $4,832, and $4,181 in 2015, 2014 and 2013, respectively. These amounts are net of customer and grant reimbursed research and development. In 2013, the Company obtained a Minnesota research and development tax credit of $567, which lowered the research and development expenditures for the year.

IntriCon owns a number of United States patents which cover a number of product designs and processes. Although the Company believes that these patents collectively add value to the Company, the costs associated with the submission of patent applications are expensed as incurred given the uncertainty of the patents providing future economic benefit to the Company.

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Regulation. A large portion of our business operates in a marketplace subject to extensive and rigorous regulation by the FDA and by comparable agencies in foreign countries. In the United States, the FDA regulates the design control, development, manufacturing, labeling, record keeping, and surveillance procedures for medical devices.

United States Food and Drug Administration

FDA regulations classify medical devices based on perceived risk to public health as either Class I, II or III devices. Class I devices are subject to general controls, Class II devices are subject to special controls and Class III devices are subject to pre-market approval ("PMA") requirements. While most Class I devices are exempt from pre-market submission, it is necessary for most Class II devices to be cleared by a 510(k) pre-market notification prior to marketing. 510(k) establishes that the device is "substantially equivalent" to a legally marketed predicate device which was legally marketed prior to May 28, 1976 or which itself has been found to be substantially equivalent, through the 510(k) process, after May 28, 1976. It is "substantially equivalent" if it has the same intended use and the same technological characteristics as the predicate. The 510(k) pre-market notification must be supported by data establishing the claim of substantial equivalence to the satisfaction of the FDA. The process of obtaining a 510(k) clearance typically can take several months to a year or longer. If the product is notably new or different and substantial equivalence cannot be established, the FDA will require the manufacturer to submit a PMA application for a Class III device that must be reviewed and approved by the FDA prior to sale and marketing of the device in the United States. The process of obtaining PMA approval can be expensive, uncertain, lengthy and frequently requires anywhere from one to several years from the date of FDA submission, if approval is obtained at all. The FDA controls the indicated uses for which a product may be marketed and strictly prohibits the marketing of medical devices for unapproved uses. The FDA can withdraw products from the market for failure to comply with laws or the occurrence of safety risks.

All of our current hearing aid devices are air conduction devices and, as such, are Class I medical devices, exempt from the 510(k) submission process. They are typically marketed to FDA approved manufacturers with IntriCon assisting in the design, development and production. Our ECG recorder devices are classified as Class II medical devices and have received 510(k) clearance from the FDA. Our manufacturing operations are subject to periodic inspections by the FDA, whose primary purpose is to audit the Company's compliance with the Quality System Regulations published by the FDA and other applicable government standards. Strict regulatory action may be initiated in response to audit deficiencies or to product performance problems. We believe that our manufacturing and quality control procedures are in compliance with the requirements of the FDA regulations. Our most recent FDA audit was conducted in August of 2015.

International Regulation

International regulatory bodies have established varying regulations governing product standards, packaging and labeling requirements, import restrictions, tariff regulations, duties and tax. Many of these regulations are similar to those of the FDA. We believe we are in compliance with the regulatory requirements in the foreign countries in which our medical devices are marketed.

The registration system for our medical devices in the EU requires that our quality system conform to international quality standards and that our medical devices conform to “essential requirements” set forth by the Medical Device Directive (“MDD”). Manufacturing facilities and processes under which our ECG recorder devices are produced are inspected and audited by our International Organization for Standardization (“ISO”) registrar British Standards Institute (“BSI”). Our authorized representative, CE Partner 4U, maintains our technical file and registers our products with competent authorities in all EU member states. Manufacturing facilities and processes under which all of our other medical devices are produced are inspected and audited annually by the BSI. These audits verify our compliance with the essential requirements of the MDD. These certifying bodies verify that our quality system conforms to the international quality standard ISO 13485:2003 and that our products conform to the “essential requirements” and “supplementary requirements” set forth by the MDD for the class of medical devices we produce. These certifying bodies also certify our conformity with both the quality standards and the MDD requirements, entitling us to place the “CE” mark on all of our ECG recorder devices. Our hearing aid devices typically bear the CE mark of our customers who assume regulatory responsibilities for those devices. In 2014, IntriCon obtained “CE” certification for our own hearing aid devices and we are prepared to supply these devices into the European market.

Third Party Reimbursement

The availability and level of reimbursement from third-party payers for procedures utilizing our products is significant to our business. Our products are purchased primarily by OEM customers who sell into clinics, hospitals and other end-users, who in turn bill various third party payers for the services provided to the patients. These payers, which include Medicare, Medicaid, private health insurance plans and managed care organizations, reimburse all or part of the costs and fees associated with the procedures utilizing our products.

In response to the national focus on rising health care costs, a number of changes to reduce costs have been proposed or have begun to emerge. There have been, and may continue to be, proposals by legislators, regulators and third party payers to curb these costs. The development or increased use of more cost effective treatments for diseases could cause such payers to decrease or deny reimbursement for surgeries or devices to favor alternatives that do not utilize our products. A significant number of Americans enroll in some form of managed care plan. Higher managed care utilization typically drives down the payments for health care procedures, which in turn places pressure on medical supply prices. This causes hospitals to implement tighter vendor selection and certification processes, by reducing the number of vendors used, purchasing more products from fewer vendors and trading discounts on price for guaranteed higher volumes to vendors. Hospitals have also sought to control and reduce costs over the last decade by joining group purchasing organizations or purchasing alliances. We cannot predict what continuing or future impact these practices, the existing or proposed legislation, or such third-party payer measures within a constantly changing healthcare landscape may have on our future business, financial condition or results of operations.

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Forward-Looking Statements

Certain statements included or incorporated by reference in this Annual Report on Form 10-K or the Company's other public filings and releases, which are not historical facts, or that include forward-looking terminology such as "may", "will", "believe", "anticipate", "expect", "should", "optimistic" or "continue", "estimate", "intend", "plan", "would", "could", "potential", "opportunity", "project", "forecast", "confident", "projections", "schedule", "designed", "future", "discussion", "if negative thereof or other variations thereof, are forward-looking statements (as such term is defined in Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933, and the regulations thereunder), which are intended to be covered by the safe harbors created thereby. These statements may include, but are not limited to statements in "Business," "Legal Proceedings", "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Notes to the Consolidated Financial Statements", such as the Company's ability to compete, statements concerning expected expenses and cost savings from the global restructuring, strategic alliances and their benefits, the adequacy of insurance coverage, government regulation, potential increases in demand for the Company's products, net operating loss carryforwards, the ability to meet cash requirements for operating needs, the ability to meet liquidity needs, assumptions used to calculate future levels of funding of employee benefit plans, the adequacy of insurance coverage, the impacts of new accounting pronouncements and litigation.

Forward-looking statements also include, without limitation, statements as to the Company's expected future results of operations and growth, the Company's ability to meet working capital requirements, the Company's business strategy, the expected increases in operating efficiencies, anticipated trends in the Company's body-worn device markets, the effect of compliance with environmental protection laws and other government regulations, estimates of goodwill impairments and amortization expense of other intangible assets, estimates of asset impairment, the effects of changes in accounting pronouncements, the effects of litigation and the amount of insurance coverage, and statements as to trends or the Company's or management's beliefs, expectations and opinions. Forward-looking statements are subject to risks and uncertainties and may be affected by various risks, uncertainties and other factors that can cause actual results and developments to be materially different from those expressed or implied by such forward-looking statements, including, without limitation, the risk factors discussed in Item 1A of this Annual Report on Form 10-K.

The Company does not undertake to update any forward-looking statement that may be made from time to time by or on behalf of the Company.

Available Information

The Company files or furnishes its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information with the SEC. You may read and copy any reports, statements and

other information that the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The Company's reports, proxy and information statements and other SEC filings are also available on the SEC's website as part of the EDGAR database (http://www.sec.gov).

The Company maintains an internet web site at www.IntriCon.com. The Company maintains a link to the SEC's website by which you may review its annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended.

The information on the website listed above, is not and should not be considered part of this annual report on Form 10-K and is not incorporated by reference in this document. This website is and is only intended to be an inactive textual reference.

In addition, we will provide, at no cost (other than for exhibits), paper or electronic copies of our reports and other filings made with the SEC. Requests should be directed to:

Corporate Secretary

IntriCon Corporation
1260 Red Fox Road
Arden Hills, MN 55112

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ITEM 1A. Risk Factors

You should carefully consider the risks described below. If any of the risks events actually occur, our business, financial condition or results of future operations could be materially adversely affected. This Annual Report on Form 10-K contains forward-looking statements that involve risk and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of many factors, including the risks faced by us described below and elsewhere in this Annual Report on Form 10-K.

We have experienced and expect to continue to experience fluctuations in our results of operations, which could adversely affect us.

Factors that affect our results of operations include, but are not limited to, the volume and timing of orders received, changes in the global economy and financial markets, changes in the mix of products sold, market acceptance of our products and our customer's products, competitive pricing pressures, global currency valuations, the availability of electronic components that we purchase from suppliers, our ability to meet demand, our ability to introduce new products on a timely basis, the timing of new product announcements and introductions by us or our competitors, changing customer requirements, delays in new product qualifications, and the timing and extent of research and development expenses. These factors have caused and may continue to cause us to experience fluctuations in operating results on a quarterly and/or annual basis. These fluctuations could materially adversely affect our business, financial condition and results of operations, which in turn, could adversely affect the price of our common stock.

The loss of one or more of our major customers could adversely affect our results of operations.

We are dependent on a small number of customers for a large portion of our revenues. In fiscal year 2015, our largest customer accounted for approximately 42 percent of our net sales and our five largest customers accounted for approximately 60 percent of our net sales. A significant decrease in the sales to or loss of any of our major customers could have a material adverse effect on our business and results of operations. Our revenues are largely dependent upon the ability of customers to develop and sell products that incorporate our products. No assurance can be given that our major customers will not experience financial, technical or other difficulties that could adversely affect their operations and, in turn, our results of operations.

We may not be able to collect outstanding accounts receivable from our customers.

Some of our customers purchase our products on credit, which may cause a concentration of accounts receivable among some of our customers. As of December 31, 2015, we had accounts receivable, less allowance for doubtful accounts, of $8,578, which represented approximately 45 percent of our shareholders' equity as of that date. As of that date, two customers accounted for a combined total of 27 percent of our accounts receivable. Our financial condition and profitability may be harmed if one or more of our customers are unable or unwilling to pay these accounts receivable when due.

Despite signs of improvement in economic conditions, downturns in the domestic economic environment could cause a severe disruption in our operations.

Our business has been negatively impacted by the domestic economic environment in recent years. If the economy does not continue to improve, or worsens, there could be several severely negative implications to our business that may exacerbate many of the risk factors we identified including, but not limited to, the following:

Liquidity:

- The domestic economic environment and the associated credit crisis could worsen and reduce liquidity and this could have a negative impact on financial institutions and the country's financial system, which could, in turn, have a negative impact on our business.

- We may not be able to borrow additional funds under our existing credit facility and may not be able to expand our existing facility if our lender becomes insolvent or its liquidity is limited or impaired or if we fail to meet covenant levels going forward. In addition, we may not be able to renew our existing credit facility at the conclusion of its current term in February 2019 or renew it on terms that are favorable to us.

- During the last few years the Federal Reserve Board's involvement in the purchase of U.S. government debt securities, commonly know as "quantitative easing," has caused interest rates to be lower than they would have been without such involvement. As a result of the end of quantitative easing in October 2014, and the recent decision by the Federal Reserve to raise the target federal funds rate, interest rates could begin to rise, which could disrupt domestic and world markets and could adversely affect our liquidity and results of operations.

Demand:

- Any deterioration in the economy or a return to recession could result in lower sales to our customers. Additionally, our customers may not have access to sufficient cash or short-term credit to obtain our products or services.

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Prices:

- Certain markets could experience deflation, which would negatively impact our average prices and reduce our margins.

Health care policy changes, including U.S. health care reform legislation signed in 2010, may have a material adverse effect on us.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. The legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on all U.S. medical device sales beginning in January 2013. Under the legislation, the total cost to the medical device industry is expected to be approximately $30 billion over ten years. This significant increase in the tax burden on our industry could have a material, negative impact on our results of operations and our cash flows either directly, through taxes on us, or indirectly through others in our value chain being subject to the tax. Although the direct impact of the excise tax is expected to be immaterial on us, if facts or circumstances change in our business relationships, we could be subject to customer pricing pressures or required to pay additional taxes under the rules. Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions, could meaningfully change the way health care is developed and delivered, and may materially impact numerous aspects of our business. In December 2015, legislation suspended the 2.3% medical device tax for fiscal years 2016 and 2017, but the tax would go back into effect on December 31, 2017 unless further legislation is adopted.

If we are unable to continue to develop new products that are inexpensive to manufacture, our results of operations could be adversely affected.

We may not be able to continue to achieve our historical profit margins due to advancements in technology. The ability to continue our profit margins is dependent upon our ability to stay competitive by developing products that are technologically advanced and inexpensive to manufacture.

Our need for continued investment in research and development may increase expenses and reduce our profitability.

Our industry is characterized by the need for continued investment in research and development. If we fail to invest sufficiently in research and development, our products could become less attractive to existing and potential customers and our business and financial condition could be materially and adversely affected. As a result of the need to maintain or increase spending levels in this area and the difficulty in reducing costs associated with research and development, our operating results could be materially harmed if our research and development efforts fail to result in new products or if revenues fall below expectations. In addition, as a result of our commitment to invest in research and development, management believes that research and development expenses as a percentage of revenues could increase in the future.

We operate in a highly competitive business and if we are unable to be competitive, our financial condition could be adversely affected.

Several of our competitors have been able to offer more standardized and less technologically advanced hearing and professional audio communication products at lower prices. Price competition has had an adverse effect on our sales and margins. Many of our competitors are larger than us and have greater research and development resources, marketing and financial resources, manufacturing capability and customer support organizations than we have. There can be no assurance that we will be able to maintain or enhance our technical capabilities or compete successfully with our existing and future competitors.

Merger and acquisition activity in our hearing health market has resulted in a smaller customer base. Reliance on fewer customers may have an adverse effect on us.

Several of our customers in the hearing health market have undergone mergers or acquisitions, resulting in a smaller customer base with larger customers. If we are unable to maintain satisfactory relationships with the reduced customer base, it may adversely affect our operating profits and revenue.

Unfavorable legislation in the hearing health market may decrease the demand for our products, and may negatively impact our financial condition.

In some of our foreign markets, government subsidies cover a portion of the cost of hearing aids. A change in legislation that would reduce or eliminate these subsidies could decrease the demand for our hearing health products. This could result in an adverse effect on our operating results. We are unable to predict the likelihood of any such legislation.

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Our failure, or the failure of our customers, to obtain required governmental approvals and maintain regulatory compliance for regulated products would adversely affect our ability to generate revenue from those products.

The markets in which our business operates are subject to extensive and rigorous regulation by the FDA and by comparable agencies in foreign countries. In the United States, the FDA regulates the design control, development, manufacturing, labeling, record keeping, and surveillance procedures for our medical devices and those of our customers

The process of obtaining marketing clearance or approvals from the FDA for new products and new applications for existing products can be time-consuming and expensive, and there is no assurance that such clearance/approvals will be granted, or that the FDA review will not involve delays that would adversely affect our ability to commercialize additional products or additional applications for existing products. Some of our products in the research and development stage may be subject to a lengthy and expensive pre-market approval process with the FDA. The FDA has the authority to control the indicated uses of a device. Products can also be withdrawn from the market due to failure to comply with regulatory standards or the occurrence of unforeseen problems. The FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us.

The registration system for our medical devices in the EU requires that our quality system conform to international quality standards. Manufacturing facilities and processes under which our ECG recorder devices and hearing aid devices are produced, are inspected and audited by various certifying bodies. These audits verify our compliance with applicable requirements and standards. Further, the FDA, various state agencies and foreign regulatory agencies inspect our facilities to determine whether we are in compliance with various regulations relating to quality systems, such as manufacturing practices, validation, testing, quality control, product labeling and product surveillance. A determination that we are in violation of such regulations could lead to imposition of civil penalties, including fines, product recalls or product seizures, suspensions or shutdown of production and, in extreme cases, criminal sanctions, depending on the nature of the violation.

Further, to the extent that any of our customers to whom we supply products become subject to regulatory actions or delays, our sales to those customers could be reduced, delayed or suspended, which could have a material adverse effect on our sales and earnings.

Implementation of our growth strategy may not be successful, which could affect our ability to increase revenues.

Our growth strategy includes developing new products and entering new markets, as well as identifying and integrating acquisitions. Our ability to compete in new markets will depend upon a number of factors including, among others:

- our ability to create demand for products in new markets;
- our ability to manage growth effectively;
- our ability to strengthen our sales and marketing presence;
- our ability to successfully identify, complete and integrate acquisitions;
- our ability to respond to changes in our customers' businesses by updating existing products and introducing, in a timely fashion, new products which meet the needs of our customers;
- the quality of our new products; and
- our ability to respond rapidly to technological change.

The failure to do any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. In addition, we may face competition in these new markets from various companies that may have substantially greater research and development resources, marketing and financial resources, manufacturing capability and customer support organizations.

We have foreign operations in Singapore, Indonesia, the United Kingdom and Germany, and various factors relating to our international operations could affect our results of operations.