MISONIX INC Form 10-K September 26, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-K

-	N /	r	1	i_	$\boldsymbol{\cap}$		- \	
(V	а	rı	K	O	n	e)

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

For the fiscal year ended June 30, 2008

OR

o 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) 11-2148932 (I.R.S. Employer Identification No.)

1938 New Highway, Farmingdale, New

York

11735

(Address of principal executive offices)

(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. o Yes x 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.

o Yes x 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. x Yes o 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. x

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 o Accelerated filer o

Non-accelerated filer o Smaller reporting company x

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

The aggregate market value of the voting stock held by non-affiliates of the registrant on December 31, 2007 (computed by reference to the closing price of such stock on such date) was approximately \$28,878,000.

There were 7,001,369 shares of Common Stock outstanding at September 24, 2008.

INCORPORATED BY REFERENCE

None

With the exception of historical information contained in this Form-10K, 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. Investors are cautioned that forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the statements made. The 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, potential acquisitions, consumer and industry acceptance, litigation and/or contemplated 510 (k) filings, the ability to achieve and maintain profitability in the Company's 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. The Company disclaims any obligation to update its forward-looking statements.

PART I

Item 1. Business.

Overview

MISONIX, INC. ("Misonix" or the "Company") is a New York corporation which, through its predecessors, was first organized in 1959. The Company designs, manufactures, markets and develops minimally invasive ultrasonic medical device products. The Company also develops and markets ultrasonic equipment for use in the scientific and laboratory markets and ductless fume enclosures for filtration of gaseous contaminates in the laboratory and forensic markets.

The Company's operations outside the United States consist of a 100% ownership in Labcaire Systems, Ltd. ("Labcaire"), which is based in North Somerset, England. This business consists of designing, manufacturing, servicing and marketing the ISIS and Guardian endoscope disinfection systems and air-handling systems for the protection of personnel, products and the environment from airborne hazards. The Company also has a 60% ownership in UKHIFU Limited ("UKHIFU"), located in Bristol, England, which is the sales/marketing and service arm of the Company for the ablation of prostate cancer in the United Kingdom ("UK"). The Company has a 100% ownership in Misonix, Ltd. which is located in North Somerset, England. This business is the sales, marketing, distribution and servicing arm for the Company's medical device products in Europe.

The Company's 95% owned subsidiary, Acoustic Marketing Research, Inc. doing business as Sonora Medical Systems ("Sonora"), located in Longmont, Colorado, is an ISO 9001 certified depot level repair facility for MRI and diagnostic ultrasound subsystems, as well as a factory level repair center for diagnostic ultrasound transducers. In addition, Sonora manufactures test equipment to appropriately diagnose failures with ultrasound systems and probes and to establish baseline performance and maintain quality assurance programs for ultrasound systems.

The Company's 100% owned subsidiary, Hearing Innovations, Inc. ("Hearing Innovations"), is a development company with patented HiSonic ultrasonic technology for the treatment of profound deafness and tinnitus.

In fiscal 2008, approximately 46% of the Company's net sales were to foreign markets. Labcaire, which manufactures and sells the Company's fume enclosure line as well as its own range of laboratory and medical environmental control products, represents approximately 64% of the Company's net sales to foreign markets. Labcaire also distributes the Company's ultrasonic equipment for use in scientific and industrial markets, predominately in the UK. Sales by the Company in other major industrial countries are made primarily through distributors. There were no additional risks for products sold by Labcaire as compared to other products marketed and sold by Misonix in the United States. Labcaire experiences minimal currency exposure since the major portion of its revenues are from the UK. Labcaire revenues outside the UK are predominately remitted in British Pounds.

Misonix represented approximately 19% of the net sales to foreign markets in fiscal 2008. These sales had no additional risks as most sales are secured by letters of credit and are remitted to Misonix in U.S. currency.

Sonora represented approximately 11% of the net sales to foreign markets in fiscal 2008. These sales had additional risks as most sales are not secured by letters of credit or do not involve a long term customer where credit risk is minimal. These sales are remitted to Sonora in U.S. currency.

Misonix, Ltd. sales represented approximately 1% of net sales to foreign markets in fiscal 2008 and were invoiced in Euros. These sales had the normal credit risks.

UKHIFU operates in the UK and invoices in British pounds, its sales represented 5% of net sales to foreign markets in fiscal 2008.

Medical Devices

In October 1996, the Company entered into a twenty-year license agreement (the "USS License") with United States Surgical, a unit of Covidien Ltd. ("USS"). The USS License covers the further development of the Company's medical technology relating to ultrasonic cutting, which uses high frequency sound waves to coagulate and divide tissue for both open and laproscopic surgery. The USS License gives USS exclusive worldwide marketing and sales rights for this technology and device. Total sales of this device were approximately \$3,629,000, \$4,464,000 and \$4,461,000 for the fiscal years ended June 30, 2008, 2007 and 2006, respectively. Total royalties from sales of this device were approximately \$691,000, \$827,000 and \$810,000 for the fiscal years ended June 30, 2008, 2007 and 2006, respectively.

In June 2002, the Company entered into a ten-year worldwide, royalty-free, distribution agreement with Byron Medical, Inc. ("Byron") for the sale, marketing and distribution of the Lysonix soft tissue aspirator used for cosmetic surgery. This agreement is a standard agreement for such distribution in that it specifies the product to be distributed, the terms of the agreement and the price to be paid for product covered under the agreement. Total sales of this device were approximately \$1,596,000, \$501,000 and \$1,195,000 for the fiscal years ended June 30, 2008, 2007 and 2006, respectively.

Fibra Sonics, Inc.

On February 8, 2001, the Company acquired certain assets and liabilities of Fibra Sonics, Inc. ("Fibra Sonics"), a Chicago-based, privately held producer and marketer of ultrasonic medical devices for approximately \$1,900,000. This acquisition gave the Company access to three important new medical markets, namely, neurology with its Neuro Aspirator product, urology with the Company's lithotripsy product and ophthalmology. Subsequent to the acquisition, the Company relocated the assets of Fibra Sonics to the Company's Farmingdale facility.

UKHIFU Limited

On March 27, 2006, the Company, through its wholly owned subsidiary Misonix, Ltd., acquired a 60% equity position in UKHIFU from Imaging Equipment which owns the remaining 40%. UKHIFU is in the business providing Sonablate 500® equipment to doctors, on a fee for service basis, to use for the ablation of cancerous tissue in the prostate and is the sales/marketing and service arm of the Company in the UK for Sonablate 500 equipment.

In addition to the original investment, the Company made payments of approximately \$50,000 and \$60,000 to Imaging Equipment during the years ended June 30, 2008 and June 30, 2007, respectively. The additional payments were recorded as goodwill.

Focus Surgery, Inc.

On May 3, 1999, the Company entered into an agreement with Focus Surgery, Inc. ("Focus") to obtain a 20% equity position in Focus for \$3,050,000 and representation on its Board of Directors. Additionally, the Company has options and warrants to purchase an additional 5% of the equity of Focus. Focus is located in Indianapolis, Indiana. The agreement provides for a series of development and manufacturing agreements whereby the Company would upgrade existing Focus products, currently the Sonablate 500, and create new products based on high intensity focused ultrasound ("HIFU") technology for the non-invasive treatment of tissue for certain medical applications. The Company has the right to utilize HIFU technology for the treatment of both benign and cancerous tumors of the breast, liver and kidney and the right of first refusal to purchase 51% of the equity of Focus. In February 2001, the Company exercised its right to start research and development for the treatment of kidney and liver tumors utilizing HIFU technology. During fiscal 2005, Focus entered into an exclusive agreement with the Company to distribute the Sonablate 500 in the European market. On July 1, 2008, the Company closed the transaction with USHIFU, LLC ("USHIFU") whereby the Company sold its equity portion in Focus to USHIFU and was paid one half of the amount of its outstanding debt plus interest owed to Misonix by Focus with the remaining amount to be paid in 18 months. On July 1, 2008, the Company received \$679,366.34 which represents one half of the outstanding debt plus interest and \$837,500 for the

Company's 2,500 shares of Series M Preferred Stock of Focus.

Hearing Innovations, Inc.

On July 14, 2004, Hearing Innovations sent all shareholders and creditors a plan for reorganization and disclosure statement. The Company committed to fund Hearing Innovations up to \$150,000 for the reorganization plan. Hearing Innovations filed for relief under Chapter 11 of the U.S. Bankruptcy Code in September 2004. The Plan of Reorganization of Hearing Innovations was confirmed by the court on January 13, 2005. Based upon the final decree, and the approval by the court of the Bankruptcy Plan, the Company owns 100% of the equity in Hearing Innovations.

_

Sonora Medical Systems

On November 16, 1999, the Company acquired a 51% interest in Sonora for approximately \$1,400,000. Sonora authorized and issued new common stock for the 51% interest. Sonora utilized the proceeds of such sale to increase inventory and expand marketing, sales, and research and development efforts. An additional 4.7% was acquired from the principals of Sonora on February 25, 2000, for \$208,000, bringing the acquired interest to 55.7%. The principals of Sonora sold an additional 34.3% to Misonix on June 1, 2000 for approximately \$1,407,000, bringing the acquired interest to 90%. The acquisition of Sonora was accounted for under the purchase method of accounting. Accordingly, results of operations for Sonora are included in the consolidated statement of income from the date of acquisition and acquired assets and liabilities have been recorded at their estimated fair values at the date of acquisition. The excess of the cost of the acquisition (\$2,957,000 plus acquisition costs of \$101,000, which includes a broker fee of \$72,000) over the fair value of net assets acquired was \$1,622,845 and is being treated as goodwill. During fiscal 2007, William H. Phillips, a principal of Sonora, exercised his right to require Misonix to purchase his 5% equity portion in Sonora based upon a formula of two times sales. At June 30, 2007, the Company acquired 1.25% for approximately \$296,000 of which \$242,000 was recorded as goodwill, a reduction in minority interest of \$38,000 and \$16,000 was included in interest expense. During the year ended June 30, 2008, the Company acquired the remaining 3.75% for approximately \$918,000 of which \$727,000 was recorded as goodwill, a reduction of minority interest of \$112,000 and \$79,000 was included in interest expense bringing the total acquired interest to 95%.

On July 27, 2000, Sonora acquired 100% of the assets of CraMar Technologies, Inc. ("CraMar"), an ultrasound equipment servicer for approximately \$311,000. The assets of the Colorado-based, privately-held operations of CraMar were relocated to Sonora's facility in Longmont, Colorado. The acquisition was accounted for under the purchase method of accounting. Accordingly, acquired assets have been recorded at their estimated fair values at the date of acquisition. The excess of the cost of the acquisition (\$272,908 plus acquisition costs of \$37,898, which includes a broker fee of \$25,000) over the fair value of net assets acquired was \$257,899 and is being treated as goodwill.

On October 12, 2000, Sonora acquired the assets of Sonic Technologies Laboratory Services ("Sonic Technologies"), an ultrasound acoustic measurement and testing laboratory, for approximately \$320,000. The assets of the Hatboro, Pennsylvania-based operations of privately-held Sonic Technologies were relocated to Sonora's facility in Longmont, Colorado. The acquisition was accounted for under the purchase method of accounting. Accordingly, acquired assets and liabilities have been recorded at their estimated fair values at the date of acquisition. The excess of the cost of the acquisition (\$270,000 plus acquisition costs of \$51,219, which includes a broker fee of \$25,000) over the fair value of net assets acquired was \$301,219 and is being treated as goodwill.

Laboratory and Scientific Products

The Company's other revenue producing activities consist of the manufacture and sale of Sonicator ultrasonic liquid processors and cell disruptors, AuraTM ductless fume hood products and ISIS, Guardian and Jet AER autoscope reprocessing, disinfecting and rinsing equipment.

Since 1959, the Sonicator line of products has been at the leading edge of ultrasound technology for the laboratory. Misonix has developed the application of sonication as it is currently used in research laboratories to disrupt cells and bacteria, accelerate chemical reactions in the extraction of proteins from cells and in genomic and proteomic research. Over the years our engineering staff has greatly improved the design and performance of the instrument to include a variety of ultrasonic generators, horns and probe accessories to handle virtually any laboratory application and the term Sonicator has become synonymous with ultrasonic liquid processing. The Company's products are proprietary in that they primarily utilize ultrasound as a technology base to solve laboratory, scientific and medical issues. The Company has technical expertise in ultrasound and utilizes ultrasound in many applications, which management believes makes the Company unique. The Company's ultrasound technology is the core surrounding its business model.

The Aura ductless fume hood products offer 40 years of experience in providing safe work environments to medical, pharmaceutical, biotech, semiconductor, law enforcement, federal and local government laboratories. We manufacture a complete line of ductless fume enclosures to control and eliminate hazardous vapors, noxious odors and particulates in the laboratory. All fume enclosure products utilize either activated carbon or HEPA filters to capture contaminants and are a cost effective alternative to standard laboratory fume hoods that require expensive ductwork to vent contaminants to the outside. Misonix also offers laminar airflow stations and PCR enclosures. Misonix Ductless Fume Hoods meet or exceed applicable OSHA, ANSI, NFPA, SEFA and ASHRAE standards for ductless fume hoods. School Demonstration Ductless Fume Hoods have proven to be a valuable addition to hundreds of high school science laboratories. Multiple application filters allow for the use of a variety of chemicals and a clear back panel enables students to view demonstrations from all sides.

The technology used in the Aura ductless fume enclosures has also been adapted for specific uses in crime laboratories. The Forensic Evidence Cabinet protects wet evidence from contamination while it is drying and simultaneously protects law enforcement personnel from evidence that can be noxious and hazardous. The Cyanoacrylate (liquid glue) Fuming Chamber is used by fingerprinting experts to develop fingerprints on non-porous surfaces while providing protection from hazardous cyanoacrylate fumes.

In June 1992, the Company initially acquired an 81.4% interest in Labcaire for \$545,169. The total acquisition cost exceeded the fair value of the net assets acquired by \$241,299, which is being treated as goodwill. The balance of the capital stock of Labcaire was owned by current and former employees of Labcaire who, under a purchase agreement (the "Labcaire Agreement"), sold one-seventh of their total holdings of Labcaire shares to the Company in each of seven consecutive years, commencing with the fiscal year ended June 30, 1996. As of June 30, 2003 the Company owned 100% of Labcaire. Under the Labcaire Agreement, the Company purchased such shares at a price equal to one-seventh of each executive's prorata share of 8.5 times Labcaire's earnings before interest, taxes, and management charges for the preceding fiscal year, which amount is being treated as goodwill. Total goodwill associated with Labcaire is \$1,214,808 of which \$1,063,294 remains at June 30, 2008.

3

Labcaire has developed, manufactures and sells an automatic endoscope disinfection system ("Autoscope"), which is used predominantly in hospitals. The Autoscope disinfects and rinses several endoscopes while abating the noxious disinfectant fumes produced by the cleaning process. In fiscal 2007, Labcaire introduced the ISIS Autoscope version to incorporate a number of enhancements to comply with the UK HTM 2030 guidelines. HTM 2030 guidelines, among other things, describe the handling of endoscopes to minimize the transfer of bio matter from one patient to the next. Labcaire's business also consists of designing, manufacturing, servicing and marketing air handling systems for the protection of personnel, products and the environment from airborne hazards. These systems are similar to the Aura fume enclosures in that they extract noxious fumes through a series of filters to introduce clean air back into the environment, but have expanded their applications. There are no additional risks for products sold by Labcaire as compared to other products marketed and sold by the Company in the United States. Labcaire experiences minimal currency exposures since a major portion of its revenues are from the UK. Revenues outside the UK are remitted in British Pounds. Labcaire is also the UK distributor of the Company's ultrasonic laboratory and scientific products. Labcaire manufactures class 100 biohazard safety enclosures, used in laboratories to provide sterile environments and to protect lab technicians from airborne contaminants, and class 100 laminar flow enclosures. Labcaire also manufactures the Company's ductless fume enclosures for the European market and sells the enclosures under its trade name.

Market and Customers

Medical Devices

The Company relies on its licensee, USS, a significant customer, for marketing its ultrasonic Auto Sonix surgical device. The Company relies on distributors such as Byron, a wholly owned subsidiary of Mentor Corporation ("Mentor"), Aesculap, Inc. and independent distributors for the marketing of its other medical products. The Company sells its SonicOne Wound Debridement System through independent representatives throughout the United States and through distributors outside the United States.

Sonora relies on direct salespersons and distributors for the marketing of its ultrasonic medical devices. Focus is utilizing the Company, in an exclusive agreement, to distribute the Sonablate 500 in the European market and Russia, which allows the Company to sell directly to end users such as doctors, hospitals and distributors. The Company sells the Sona Star Ultrasonic Surgical Aspiration System directly to end users and distributors internationally.

In June 2002, the Company entered into a ten-year worldwide, royalty-free, distribution agreement with Mentor for the sale, marketing and distribution of the Lysonix 2000/3000 soft tissue aspirator used for cosmetic surgery. In June 2007, the Company terminated the supply and distribution agreement due to Mentor's breach of the agreement. In September 2007, the Company completed a new agreement with Mentor for domestic sales of its ultrasound assisted liposuction product, the Lysonix 3000. Mentor agreed to minimum purchase order provisions for the Lysonix 3000 for a one year term commencing September 30, 2007, and successive annual renewals upon mutual agreement by the companies.

Laboratory and Scientific Products

The Company relies on direct salespersons, distributors, manufacturing representatives and catalog listings for the marketing of its laboratory and scientific products. The Company currently sells its products through five manufacturers' representative firms, twenty distributors in the United States and fourteen internationally. The Company currently employs one direct sales person who operates outside the Company's offices and conducts direct marketing on a regional basis.

The market for the Company's ductless fume enclosures includes laboratory or scientific environments in which workers may be exposed to noxious fumes or vapors. The products are suited to laboratories in which personnel

perform functions which release noxious fumes or vapors (including hospital and medical laboratories), industrial processing (particularly involving the use of solvents) and soldering, and other general chemical processes. The products are particularly suited to users in the pharmaceutical, semiconductor, biotechnology, and forensic industries.

The largest market for the Company's Sonicator includes research and clinical laboratories worldwide. In addition, the Company has expanded its sales of the ultrasonic processor into industrial markets such as paint, pigment, ceramic and pharmaceutical manufacturers.

4

In fiscal 2008, approximately 46% of the Company's net sales were to foreign markets. Labcaire acts as the European distributor of the Company's laboratory and scientific products and manufactures and sells the Company's fume enclosure line as well as its own range of laboratory and hospital environmental control products, such as the ISIS Autoscope cleaning device. Sales by the Company in other major industrial countries are made through distributors.

Manufacturing and Supply

Medical Devices

The Company manufactures and assembles its medical device products and Focus 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.

Sonora manufactures and refurbishes its products at its facility in Longmont, Colorado. Sonora is not dependent upon any single source of supply and has no long-term supply agreements. The Company does not believe that Sonora will encounter difficulty in obtaining materials, supplies and components adequate for its anticipated short-term needs.

Laboratory and Scientific Products

The Company manufactures and assembles the majority of its laboratory and scientific 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 believes that it will not encounter difficulty in obtaining materials, supplies and components adequate for its anticipated short-term needs. The Company is not dependent upon any single source of supply and has no long-term supply agreements.

Labcaire manufactures and assembles its products at its facility located in North Somerset, England. The Company does not believe that Labcaire will encounter difficulty in obtaining materials, supplies and components adequate for its anticipated short-term needs. Labcaire is not dependent upon any single source of supply and has no long-term supply agreements.

Competition

Medical Devices

Competition in the medical device products and the medical repair and refurbishment industry is rigorous with many companies having significant capital resources, large research laboratories and extensive distribution systems in excess of the Company's. Some of the Company's major competitors are Johnson & Johnson, Inc., Valley Lab, a division of Tyco Healthcare, Integra Life Sciences, Inc., EDAP, TMS S.A., Ambassador Medical, a subsidiary of GE Medical, Philips and Siemens.

Laboratory and Scientific Products

Competitors in the ultrasonic industry for laboratory and scientific products range from large corporations with greater production and marketing capabilities to smaller firms specializing in single products. The Company believes that its significant competitors in the manufacturing and distribution of industrial ultrasonic devices are Branson Ultrasonics, a division of Emerson Electric Co., and Sonics & Materials, Inc. It is possible that other companies in the industry are currently developing products with the same capabilities as those of the Company. The Company believes that the features of its Sonicator and the Company's customer assistance in connection with particular applications give the

Sonicator a competitive advantage over comparable products.

The Company believes that specific advantages of its fume enclosures include efficiency and other product features, such as durability and ease of operation. Ductless fume enclosure advantages are the quality of the product and versatility of applications. The principal competitors for the Company's ductless fume enclosure are Captair, Inc., Air Science Technologies, Air Cleaning Systems, Inc. and Lancer UK Ltd.

Regulatory Requirements

The Company's medical device products are subject to the regulatory requirements of the U.S. Food and Drug Administration ("FDA"). A medical device as defined by the FDA is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory which is recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to such listings, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or animals, or intended to affect the structure or any function of the body of man or animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes (a "medical device"). The Company's products that are subject to FDA regulations for product labeling and promotion comply with all applicable regulations. The Company is listed with the FDA as a Medical Device manufacturer and has the appropriate FDA Establishment Numbers in place. The Company has a post-market monitoring system in place such as Complaint Handling and Medical Device Reporting procedures. All current devices manufactured and sold by the Company have all the necessary regulatory approvals. The Company is not aware of any situations which would be materially adverse at this time and neither has the FDA sought legal remedies available, nor have there been any violations of its regulations alleged, against the Company at present.

5

Patents, Trademarks, Trade Secrets and Licenses

Pursuant to a royalty free license agreement with an unaffiliated third party, the Company has the right to use the trademark "Sonicator" in the United States. The Company also owns trademark registrations for Mystaire in both England and Germany.

The following is a list of the U.S. patents which have been issued to the Company:

Number	Description	Issue Date	Expiration Date
4,920,954	Cavitation Device - relating to the Alliger System for applying ultrasonic arteries using a generator, transducer and titanium wire.	05/01/1990	08/05/2008
5,026,167	Fluid Processing - relating to the Company's environmental control product line for introducing ozone and liquid into the cavitation zone for an ultrasonic probe.	06/25/1991	10/19/2009
5,032,027	Fluid processing - relating to the Company's environmental control product line for the intimate mixing of ozone and contaminated water for the purpose of purification.	07/16/1991	10/19/2009
5 0 40 00 <i>6</i>	W' 'd l d l d' d d C L All' C d C l l '	00/02/1002	12/24/2010
5,248,296	Wire with sheath - relating to the Company's Alliger System for reducing transverse motion in its catheters.	09/23/1993	12/24/2010
5,306,261	Cuidavira guidas ralating to the Company's Alligar System for a aetheter	04/26/1994	01/22/2013
3,300,201	Guidewire guides - relating to the Company's Alliger System for a catheter with collapsible wire guide.	04/20/1994	01/22/2013
	with contapsions who guide.		
5,443,456	Guidewire guides - relating to the Company's Alliger System for a catheter with collapsible wire guide.	08/22/1995	02/10/2014
5.371.429*	Flow-thru transducer - relating to the Company's liposuction system and its	12/06/1994	09/28/2013
- , ,	ultrasonic laboratory and scientific products for an electromechanical transducer device.		
5,397,293	Catheter sheath - relating to the Company's Alliger System for an ultrasonic device with sheath and transverse motion damping.	03/14/1995	11/25/2012
5,419,761*	Liposuction - relating to the Company's liposuction apparatus and associated method.	05/30/1995	08/03/2013
D 400 746		05/11/1000	05/11/0012
D409 746	Cannula for ultrasonic probe.	05/11/1999	05/11/2013
D408 529	Cannula for ultrasonic probe.	04/20/1989	04/20/2013
D 100 32)	Camilla for all asome proce.	0 1/20/1707	0 1/20/2013
722 3267	Ultrasonic probe with detachable slidable cauterization forceps.	02/06/2004	02/06/2024
D478165	Cannula for ultrasonic probe.	08/05/2003	08/05/2017
6			

Number 5,465,468	Description Flow-thru transducer - relating to the method of making an		Expiration Date 12/06/2014
, ,	electromechanical transducer device to be used in conjunction with the Company's soft tissue aspiration system and ultrasonic laboratory and scientific products.		
5,516,043	Atomizer horn - relating to an ultrasonic atomizing device, which is used in the Company's laboratory and scientific products.	05/14/1996	06/30/2014
5,527,273*	Ultrasonic probes - relating to an ultrasonic lipectomy probe to be used with the Company's soft tissue aspiration technology.	06/18/1996	10/6/2014
5,769,211	Autoclavable switch - relating to a medical handpiece with autoclavable rotary switch to be used in medical procedures.	06/23/1998	01/21/2017
5,072,426	Shock wave hydrophone with self-monitoring feature.	12/10/1991	02/08/2011
5,151,084	Ultrasonic needle with sleeve that includes a baffle.	09/29/1992	07/29/2011
5,562,609	Ultrasonic surgical probe.	10/08/1996	10/07/2014
5,562,610	Needle for ultrasonic surgical probe.	10/08/1996	10/07/2014
6,033,375	Ultrasonic probe with isolated and Teflon coated outer cannula.	03/07/2000	12/23/2017
6,270,471	Ultrasonic probe with isolated outer cannula.	08/07/2001	12/23/2017
6,443,969	Ultrasonic blade with cooling.	09/03/2002	08/15/2020
6,379,371	Ultrasonic blade with cooling.	04/30/2002	11/15/2019
6,375,648	Infiltration cannula with Teflon coated outer surface.	04/23/2002	10/02/2018
6,326,039	Skinless sausage or frankfurter manufacturing method and apparatus utilizing reusable deformable support.	12/04/2001	10/31/2020
D565,444	Testing device for acoustic probes and systems	04/01/08	1/29/2021
6,920,776	Apparatus and methods for interfacing acoustic testing apparatus with acoustic probes and systems	07/26/05	11/05/2024
6,928,856	Apparatus and methods for interfacing acoustic testing apparatus with acoustic probes and systems	08/16/05	11/05/2024
7,007,539	Apparatus and methods for interfacing acoustic testing apparatus with acoustic probes and systems	03/07/06	04/28/2023
7,028,529	Apparatus and methods for testing acoustic probes and systems	04/18/06	04/28/2023

7,155,957	Apparatus and methods for testing acoustic probes and systems	01/02/07	12/27/2025
7,278,289	Apparatus and methods for testing acoustic probes and systems	10/09/07	04/28/2023
7			

Number	Description	Issue Date	Expiration Date
6,322,832	Manufacturing method and apparatus utilizing reusable deformable	11/27/2001	10/31/2020
	support.		
6,146,674	Method and device for manufacturing hot dogs using high power ultrasound.	11/14/2000	05/27/2019
6,063,050	Ultrasonic dissection and coagulation system.	05/16/2000	10/16/2017
6,036,667	Ultrasonic dissection and coagulation system.	03/14/2000	08/14/2017
6,582,440	Non-clogging catheter for lithotrity.	06/24/2003	12/26/2016
6,578,659	Ultrasonic horn assembly.	06/17/2003	12/01/2020
6,454,730	Thermal film ultrasonic dose indicator.	09/24/2002	04/02/2019
6,613,056	Ultrasonic probe with low-friction bushings.	09/02/2003	02/17/2019
6,648,839	Ultrasonic medical treatment device for RF cauterization and related method.	11/18/2003	05/08/2022
6,660,054	Fingerprint processing chamber with airborne contaminant containment and adsorption.	12/09/2003	09/10/2021
6,736,814	Ultrasonic medical treatment device for bipolar RF cauterization and related method.	05/18/2004	02/28/2022
6,799,729	Ultrasonic cleaning probe.	10/05/2004	10/05/2021
6,869,439	Ultrasonic dissector.	03/22/2005	03/22/2022
6,902,536	RF cauterization and ultrasonic ablation.	06/07/2005	06/07/2022
7,004,282	Ultrasonic horn	02/28/2006	10/28/2022
5,151,083	Apparatus for Eliminating Air Bubbles in an Ultrasonic Surgical Device	09/29/1992	07/29/2011
6,377,693**	Tinnitus masking using ultrasonic signals	06/23/1994	06/23/2014
6,173,062**	Frequency transpositional hearing aid with digital and single sideband modulation	03/16/1994	03/16/2014
6,169,813**	Frequency transpositional hearing aid with single sideband modulation	03/16/1994	03/16/2014
5,663,727**	Frequency response analyzer and shaping apparatus and digital hearing enhancement apparatus and method utilizing the same	06/23/1995	06/23/2015
* Patents vali	d also in Japan. Europe and Canada.		

^{*} Patents valid also in Japan, Europe and Canada. ** Owned by Hearing Innovations, Inc.

The following is a list of the U.S. trademarks which have been issued to the Company:

Registration	Registration			
Number	Date	Mark	Goods	Renewal Date
2,611,532	08/27/2002	Mystaire	Scrubbers Employing Fine Sprays Passing Through Mesh for Eliminating Fumes and Odors from Gases.	08/27/2012
1,219,008	12/07/1982	Sonimist	Ultrasonic and Sonic Spray Nozzle for Vaporizing Fluid for Commercial, Industrial and Laboratory Use.	03/22/2013
1,200,359	04/03/2002	Water Web	Lamination of Screens to Provide Mesh to be Inserted in Fluid Stream for Mixing or Filtering of Fluids.	04/03/2013
2,051,093	03/27/2003	Misonix	Anti-Pollution Wet Scrubbers; Ultrasonic Cleaners; Spray Nozzles for Ultrasonic Cleaners.	03/27/2009
2,051,092	02/13/2003	Misonix	Ultrasonic Liquid Processors; Ultrasonic Biological Cell Disrupters; Ultrasonic Cleaners.	02/13/2009
2,320,805	02/22/2000	Aura	Ductless Fume Enclosures.	02/22/2010
2,812,718	02/10/2004	Misonix	Ultrasonic medical devices, namely, ultrasonic surgical aspirators, ultrasonic lithotripters, ultrasonic phacoemulsifiers.	02/10/2014
1,195,570	07/14/2002	Astrason	Portable Ultrasonic Cleaners featuring Microscopic Shock Waves.	07/14/2012