HARVARD BIOSCIENCE INC
Form 10-K
March 18, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2012

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 001-33957

HARVARD BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3306140**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)

84 October Hill Road, Holliston, Massachusetts 01746

(Address of Principal Executive Offices, including zip code)

(508) 893-8999

(Registrant s telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.01 par value	**The NASDAQ Global Market**
Preferred Stock Purchase Rights	

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 x

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 x

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 x 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x YES ¨ NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act. YES ¨ NO x

The aggregate market value of 24,801,502 shares of voting stock held by non-affiliates of the registrant as of June 29, 2012 was approximately $93,501,663 based on the closing sales price of the Registrant s common stock, par value $0.01 per share on that date. Shares of the registrant s common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 8, 2013, there were 30,009,333 shares of the registrant s Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s definitive Proxy Statement in connection with the 2013 Annual Meeting of Stockholders (the Proxy Statement), to be filed within 120 days after the end of the Registrant s fiscal year, are incorporated by reference into Part III of this Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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HARVARD BIOSCIENCE, INC.

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ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2012

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This Annual Report on Form 10-K contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act), each as amended. The forward-looking statements are principally, but not exclusively, contained in Item 1: Business and Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about management s confidence or expectations, our business strategy, our ability to raise capital or borrow funds to consummate acquisitions and the availability of attractive acquisition candidates, our expectations regarding future costs of product revenues, our anticipated compliance with the covenants contained in our credit facility, the adequacy of our financial resources and our plans, objectives, expectations and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, seek, expects, plans, aim, anticipates, believes, estimates, projects, predicts, intends, strategy, potential, new, goal and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in detail under the heading Item 1A. Risk Factors beginning on page 14 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as other risks described in our public filings, and you should be aware that there may be other factors, including factors of which we are not currently aware, that could cause these differences. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. Harvard Bioscience, Inc. is referred to herein as we, our, us, and the Company.

PART I

Item 1. *Business.*

Overview

Harvard Bioscience, Inc., a Delaware corporation, is a global developer, manufacturer and marketer of a broad range of specialized products, primarily apparatus and scientific instruments which are used to advance life science research and regenerative medicine. Our products are sold to thousands of researchers in over 100 countries primarily through our 850 page catalog (and various other specialty catalogs), our website, through distributors, including GE Healthcare, Thermo Fisher Scientific Inc. and VWR, and via our field sales organization. We have sales and manufacturing operations in the United States, the United Kingdom, Germany, Sweden and Spain with additional facilities in France and Canada.

Our History

Our business began in 1901 under the name Harvard Apparatus and has grown over the years with the development and evolution of modern life science tools. Our early inventions included the mechanical syringe pump in the 1950s for drug infusion and the microprocessor controlled syringe pump in the 1980s.

In March 1996, a group of investors led by our CEO and President acquired a majority of the then existing business of our predecessor, Harvard Apparatus. Following this acquisition, we redirected the focus of our Company to participate in the higher growth areas, or bottlenecks, within life science research by acquiring and licensing innovative technologies while continuing to grow the existing business through internal product development and marketing, and acquisitions. Since March 1996, we have completed 25 business or product line acquisitions related to our continuing operations and internally developed many new product lines including: new generation Harvard Apparatus syringe pumps, PHD Ultra series of syringe pumps, advanced Inspira ventilators,

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GeneQuant DNA/RNA/protein calculators, Ultrospec spectrophotometers, our microliter spectrophotometer, 2D electrophoresis products, UVM plate readers, BTX-MOS 96 well electroporation system, the BioDrop micro volume cuvette and microvolume spectrophotometer. Recently we have developed novel devices to advance the emerging field of regenerative medicine. We currently have three marketed products, the InBreath hollow organ bioreactor, the LB2 and ORCA Solid Organ Bioreactors and the PHD Ultra Nanomite stem cell therapy injection system in this field. These products are currently available for research use only unless use on humans is approved in accordance with hospital ethics committee protocols and local regulatory rules.

In July 2005, we announced plans to divest our Capital Equipment Business segment. The decision to divest this business was based on the fact that market conditions for the Capital Equipment Business segment had been such that this business did not meet our expectations and on our decision to focus our resources on the Apparatus and Instrumentation Business segment. As a result, we began reporting our Capital Equipment Business segment as a discontinued operation in the third quarter of 2005. In November 2007, we completed the sale of the assets of our Genomic Solutions Division and the stock of our Belgian subsidiary, Maia Scientific; both part of our Capital Equipment Business Segment. In September 2008, we completed the sale of the assets of our Union Biometrica Division including our German subsidiary, Union Biometrica GmbH, representing at that time the remaining portion of our Capital Equipment Business Segment.

In addition to driving growth in our core research markets, we have been investing to create new products to address what we believe is a long term growth opportunity in the emerging field of regenerative medicine. Regenerative medicine is using stem cells to repair damaged organs and to grow organs outside the body for transplant. The U.S. Department of Health and Human Services has projected that the U.S. market for regenerative medicine may be $100 billion by the end of 2020. The government s estimate appears to include the value of all regenerative medicine protocols and therapies, including potential cost savings versus current methodologies.

Our strategy in regenerative medicine is not to become a therapeutics company but instead to provide tools to researchers and clinicians in the field of regenerative medicine. These new tools currently fall into two main categories: bioreactors and synthetic scaffolds for growing tissue and organs outside the body; and injectors for stem cell therapy. These new tools we are creating are being built on our existing technologies such as our market leading Harvard Apparatus precision syringe pumps and market leading Hugo-Sachs isolated organ systems.

Our strategy in regenerative medicine is to create devices in collaboration with leading surgeons, not to discover pharmaceuticals, as creating devices like the InBreath bioreactor reduces risk compared to trying to discover new drugs; build these devices using our existing technologies and brands as this reduces the investment needed to get to market; and develop devices with significant medical value to allow us to participate on a per-procedure basis.

Our first regenerative medicine tool, the InBreath hollow organ bioreactor, was used to perform the world s first human transplant of a regenerated bronchus. Dr. Paolo Macchiarini et al reported this success in The Lancet, a leading general medicine journal, in November 2008. We have licensed this product from Dr. Macchiarini s team, and worked to make it a commercial device. During the second and the third quarters of 2010, we took orders for this product, making it what we believe is the world s first commercially available bioreactor that has been used to perform a human transplant of a regenerated organ. We believe it marks an important milestone in the development of the regenerative medicine field as the tools evolve from concepts to commercial quality products.

During the first half of 2010, one of our collaborators, Dr. Harald Ott at Massachusetts General Hospital (MGH) succeeded in regenerating a lung and subsequently transplanting it into a rat. In collaboration with Dr. Ott and MGH, we designed and developed a novel bioreactor, the LB-2 Solid organ bioreactor, that was used to grow the lung. The work was published online in Nature Medicine in July 2010. The bioreactor used by Dr. Ott was a modified version of one of our market leading Hugo-Sachs isolated organ systems.

In June 2011, the InBreath bioreactor was used for the world s first successful transplantation of a synthetic tissue engineered windpipe. For the first time in history, a patient was given a new trachea made from a

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synthetic scaffold seeded with his own stem cells in a bioreactor. The cells were grown on the scaffold inside the bioreactor for two days before transplantation into the patient. Because the cells used to regenerate the trachea were the patient s own, there has been no rejection of the transplant, and the patient is not taking immunosuppressive drugs. The patient had been suffering from late stage trachea cancer, which before this surgery would have been inoperable, and is now alive and well twenty months after the surgery. The operation was performed at the Karolinska University Hospital in Huddinge, Stockholm, by Dr. Paolo Macchiarini of the Karolinska University Hospital and Karolinska Institutet, and colleagues. Dr. Macchiarini led an international team which included people who designed and built the nanocomposite trachea scaffold, and we produced a specifically designed bioreactor used to seed the scaffold with the patient s own stem cells. The success of this transplant surgery was published in The Lancet on November 24, 2011.

In November 2011, a second patient was given a new trachea made from a synthetic scaffold seeded with his own stem cells in a bioreactor. The patient had been suffering from late stage trachea cancer. The patient was discharged from the hospital in January 2012. On March 5, 2012, this patient died. The official cause of death recorded on the death certificate was pneumonia secondary to trachea cancer. We know of no evidence that either the scaffold or the bioreactor played any part in the patient s death.

In June 2012, the InBreath bioreactors were used for the world s first and second successful laryngotracheal implants, using synthetic laryngotracheal scaffolds seeded with cells taken from the patients bone marrow. The surgeries took place at Krasnodar Regional Hospital in Krasnodar, Russia on June 19th and June 21st. Each bioreactor was loaded with a synthetic scaffold in the shape of the patient s original organ. The scaffolds were then seeded with the patient s own stem cells. Over the course of about two days, the bioreactor promoted proper cell seeding and development. Because the patients own stem cells were used, their bodies have accepted the transplants without the use of immunosuppressive drugs. The recipients of the implants are alive nine months after the surgeries. These surgeries are a part of a clinical trial funded under a $4.8 million grant provided by the Russian government to the Krasnodar Regional Hospital. The first transplant was filmed and that documentary is being broadcast on European television under the title of The Miracle of Krasnodar .

In addition to the Russian clinical trial, a European clinical trial in trachea cancer patients is expected to start in 2014. The European clinical trial is expected to enroll approximately 25 patients. This project is a consortium of European companies, hospitals and universities led by Dr. Macchiarini.

In February 2012, the US FDA approved the first trachea transplant surgery in the US. The surgery is expected to occur by mid 2013.

In addition to the bioreactors described above, we also have started the development of a clinical version of one of our market leading Harvard Apparatus research syringe pumps. The research version of this pump is called the PHD Ultra Nanomite stem cell therapy injection system. We anticipate that this pump will be used to inject cells into damaged tissue in cell therapy. We expect to submit this pump to the regulatory agencies this year for approval. In 2012 we established our own synthetic scaffold production initiative in our Holliston, Massachusetts facility.

In December 2012, our wholly owned subsidiary Harvard Apparatus Regenerative Technology, Inc. (HART) filed a registration statement on Form S-1 with the SEC for an initial public offering, or IPO. Following the IPO, HART will own our Regenerative Medicine Device (RMD) business, which develops life-saving medical devices in the field of regenerative medicine, including devices to be used by physicians for growing organs outside the body for transplant. Following the IPO, we will own more than 80% of HART s common stock. We intend to distribute our remaining interest in HART to our shareholders in a pro-rata, tax-free dividend approximately 120 days following the closing of the IPO. We have petitioned the IRS for a private letter ruling on the tax free nature of the proposed distribution. Receipt of such a private letter ruling may be considered necessary for us to proceed with the HART IPO.

While we expect the initiatives discussed above to positively impact our business, the success of these initiatives is subject to a number of factors, including fluctuations in foreign exchange rates, the current economic and financial condition and their impact on our customers and our ability to obtain credit on terms

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favorable to us, the competitiveness of our new products, the strength of our intellectual property underlying these products, the success of our marketing efforts and those of our distributors and the other factors described under the heading Item 1A. Risk Factors beginning on page 14 in this Annual Report on Form 10-K.

Our Strategy

Our goal is to become a leading provider of tools for life science research and regenerative medicine. We refer to these two segments as our core Life Science Research Tools division (LSRT) and our RMD division.

Our LSRT strategy is to have a broad range of highly specialized but relatively inexpensive products that have strong positions in niche markets in life science research. We believe that:

- having a broad product offering reduces the risk of being dependent on a single technology;
- having relatively inexpensive products reduces the volatility associated with expensive capital equipment; and
- focusing on niche markets reduces head-to-head competition with the major instrument companies.

We seek to grow this range of products through a combination of organic growth driven by internal development of new products, direct marketing, distribution channel expansion and the acquisition of closely related products. We use acquisitions to expand our product offerings because we believe we can use our well-established brands and distribution channels to accelerate the growth of these acquired products. We also believe that our expertise in operational management frequently allows us to improve profitability at acquired companies.

Our strategy in our RMD business is to (i) create devices in collaboration with leading surgeons, researchers and clinicians, (ii) build these devices using our existing technologies and brands in an effort to reduce the investment needed to get the devices to market, and (iii) develop devices with significant medical value to allow us to participate on a per-procedure basis.

Our Products

Today, our broad LSRT product range is generally targeted towards two major application areas: ADMET testing and molecular biology.

Our RMD business is targeted towards two major application areas: Bioreactors and synthetic scaffolds to grow organs outside the human body and stem cell therapy injectors to repair damaged organs.

ADMET Testing

The goal of ADMET testing is to identify compounds that have toxic side effects or undesirable physiological or pharmacological properties. These pharmacological properties consist of absorption, distribution, metabolism and elimination, which together with toxicology, form the acronym ADMET. We have a wide range of products that our customers use to help their researchers conduct better experiments on cells, tissues, organs and animals.

We primarily sell these products under the Harvard Apparatus, BTX, KD Scientific, Hugo Sachs Elektronik, Panlab, Coulbourn Instruments, CMA Microdialysis and Warner Instruments brand names. The individual sales prices of these products are mostly under $5,000 but when combined into systems such as the Hugo Sachs isolated organ system the total sales price can be over $25,000. We typically sell our ADMET products through our catalogs and website with support from technical specialists, although BTX and KD Scientific branded products are primarily sold through distributors. Some of these products are described below:

Absorption Diffusion Chambers

A diffusion chamber is a small plastic chamber with a membrane separating the two halves of the chamber used to measure the absorption of a drug into the bloodstream. The membrane can either be tissue such as

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intestinal tissue or a cultured layer of cells such as human colon cells. This creates a miniaturized model of intestinal absorption. We manufacture and sell a wide range of tissue handling products under the Warner Instruments brand name.

Distribution 96 Well Equilibrium Dialysis Plate for Serum Protein Binding Assays

Our 96 well equilibrium dialysis plate contains 96 pairs of chambers with each pair separated by a membrane. The protein target is placed on one side of the membrane and the drug on the other. The small molecule drug diffuses through the membrane. If it binds to the target, it cannot diffuse back again. If it does not bind, it will diffuse back and forth until equilibrium is established. Once equilibrium is established, the concentration of the drug can be measured thereby indicating the strength of the binding. This product is principally used for ADMET testing to determine if a drug binds to blood proteins. A certain level of reversible binding is advantageous in order to promote good distribution of a drug through the human body. However, if the binding is too strong, it may impair normal protein function and cause toxic effects. These products are part of our sample preparation product line.

Metabolism and Elimination Organ Testing Systems

Organ testing systems use glass or plastic chambers together with stimulators and recording electrodes to study organ function. Organ testing systems enable either whole organs or strips of tissue from organs such as hearts, livers and lungs to be kept functioning outside the body while researchers perform experiments with them. This typically allows for multiple studies on a single donor animal. Studies on isolated livers are useful in determining metabolism and studies on kidneys are useful in determining elimination. We market these systems under our Hugo Sachs Elektronik, Panlab, and Coulbourn Instruments brands.

Toxicology Precision Infusion Pumps and Behavioral Products

Infusion pumps, typically syringe pumps, are used to accurately infuse very small quantities of liquid, commonly drugs. Infusion pumps are generally used for long-term toxicology testing of drugs by infusion into animals, usually laboratory rats. We sell a wide range of different types of syringe pumps and many other products for infusing samples into and collecting samples from tissues, organs and animals. We sell our syringe pumps primarily under our Harvard Apparatus and KD Scientific brands.

We also design and manufacture behavioral products used in neuroscience, cardiology, psychological and respiratory studies to evaluate the effects of situational stimuli, drugs and nutritional infusions on motor and sensory, activity and learning and test behavior. Our behavioral product offerings are marketed under our Panlab, Coulbourn and CMA Microdialysis brands.

Cell Injection Systems

Cell injection systems use extremely fine bore glass capillaries to penetrate and inject drugs into or around individual cells. Cell injection systems are used to study the effects of drugs on single cells. Injection is accomplished either with air pressure or, if the drug molecule is electrically charged, by applying an electric current. We service the cell injection systems market primarily through our Warner Instruments brand.

Ventilators

Ventilators use a piston driven air pump to inflate the lungs of an anesthetized animal. Ventilators are typically used in surgical procedures common in life science research and are part of our Harvard Apparatus product line. Our Inspira ventilators have significant safety and ease of use features, such as default safety settings. We expanded our ventilator product line with the MiniVent when we acquired Hugo Sachs Elektronik and expanded our presence in anesthesia with our acquisition of International Market Supply, Ltd.

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Electroporation Products

Our BTX brand includes our electroporation products of systems and generators, electrodes and accessories for research applications including in vivo, in ovo and in vitro gene delivery, electrocell fusion and nuclear transfer cloning. Through the application of precise pulsed electrical signals, electroporation systems open small pores in cell membranes allowing genes and/or drugs to pass through the cell membranes. The principal advantages of electroporation over other transfection techniques are speed, and that electroporation does not require chemicals that can interfere with or change cell function. In 2004, we launched our BTX MOS 96 well electroporation system, which greatly increased the throughput of this otherwise essentially manual technique. In December 2010, we signed a license agreement with Cellectis that grants us the worldwide exclusive right to manufacture and sell, for research use, the full line of Cyto Pulse electroporation-based instruments.

Distributed Products

In addition to our proprietary manufactured products, we sell through our catalogs many products that are made by other manufacturers. Distributed products accounted for approximately 33.5% of our revenues for the year ended December 31, 2012. These distributed products enable us to provide our customers with a single source for their experimental needs. These complementary products consist of a large variety of devices, instruments and consumable items used in experiments involving cells, tissues, organs and animals in the fields of proteomics, physiology, pharmacology, neuroscience, cell biology, molecular biology and toxicology. We believe that many of our proprietary manufactured products are leaders in their fields; however, researchers often need complementary products in order to conduct particular experiments.

Molecular Biology

We primarily sell these products through our distributors, including GE Healthcare, under their brand names. These products are mainly scientific instruments such as spectrophotometers and plate readers that analyze light to detect and quantify a wide range of molecular and cellular processes or apparatus such as gel electrophoresis units. The instrumentation products are typically sold for prices ranging from $5,000 to $10,000. The apparatus products typically sell for less than $5,000.

We expanded our molecular biology product offerings with our September 2009 acquisition of Denville Scientific, Inc. (Denville), a distributor of molecular biology laboratory consumables, with a strong focus on liquid handling consumables utilized in research laboratories. Denville s field sales force sells these primarily Denville branded products to end users in universities and other research laboratories. This acquisition expanded our field sales capabilities and provided access to the U.S. laboratory consumables market, which is currently estimated to be an approximately $1 billion market.

Molecular Biology Spectrophotometers

A spectrophotometer is an instrument widely used in molecular biology and cell biology to quantify the amount of a compound in a sample by shining a beam of white light through a prism or grating to divide it into component wavelengths. Each wavelength in turn is shone through a liquid sample and the spectrophotometer measures the amount of light absorbed at each wavelength. Microliter spectrophotometry is a technique used to measure extremely small sample sizes. We sell a wide range of spectrophotometers under the names UltroSpec, NovaSpec, Libra, Biowave and Lightwave. Our Biochrom subsidiary manufactures these products, and we sell them primarily through our distribution arrangements with GE Healthcare and other distributors.

DNA/RNA/Protein Calculators

A DNA/RNA/protein calculator is a bench top instrument dedicated to quantifying the amount of DNA, RNA or protein in a sample. It uses a process similar to that of a molecular biology spectrophotometer. These are sold under the GeneQuant name. Our Biochrom subsidiary manufactures these products, and we primarily sell them through our distribution agreement with GE Healthcare.

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Multi-Well Plate Readers

Multi-well plate readers are widely used for high throughput screening assays in the drug discovery process. The most common format is 96 wells per plate. Plate readers use light to detect chemical interactions. Our product line includes absorbance readers and luminescence readers. Our Biochrom subsidiary manufactures these products, and we sell them primarily through distributors under our Asys Hitech and Anthos Labtec brand names.

Amino Acid Analysis Systems

An amino acid analysis system uses chromatography to separate the amino acids in a sample and then uses a chemical reaction to detect each one in turn as they flow out of the chromatography column. Amino acids are the building blocks of proteins. We sell these systems, which are more expensive than most of our products, through Biochrom s U.S. direct sales force and through distributors internationally.

Low Volume, High-Throughput Liquid Dispensers

A liquid dispenser dispenses low volumes, typically microliters, of liquids into high density microtitre plates used in high throughput screening processes in life science research. Our unique technology enables dispensing to take place without the need for contact between the droplet and the liquid already present in the plate, thereby removing any risk of cross-contamination from the process. We primarily market these products, and we sell them under distributor brand names as well as our own Asys Hitech name.

Gel Electrophoresis Systems

Gel electrophoresis is a method for separating and purifying DNA, RNA and proteins. In gel electrophoresis, an electric current is run through a thin slab of gel and the DNA, RNA or protein molecules separate out based on their charge and size. The gel is contained in a plastic tank with an associated power supply. We market these products under our Scie-Plas and Hoefer brands. Approximately 28% of Hoefer revenues come from a distribution agreement with GE Healthcare. Hoefer also markets its products through other distributors and through a catalog/web distribution channel under the Hoefer name. We expanded our presence in this market with the acquisition of Denville in September 2009.

Consumables

Our offering of molecular biology laboratory consumables with a liquid handling focus consists primarily of such products as pipettes, pipette tips, autoradiography film, gloves, thermal cycler accessories and reagents, which we sell through our U.S. field sales force. Our Denville Scientific business services this market. In February 2012 we purchased AHN Biotechnologie GmbH (AHN). AHN is a manufacturer of laboratory consumables.

Our Customers

Our end-user customers are primarily research scientists at universities and government laboratories, including the U.S. National Institute of Health, or NIH and pharmaceutical and biotechnology companies. Our academic customers have included major colleges and universities such as Baylor University, Cambridge University, Harvard University, Johns Hopkins University, Massachusetts Institute of Technology, Yale University and the University of Texas MD Anderson Center. Our pharmaceutical and biotechnological customers have included pharmaceutical companies and research laboratories such as Amgen, Inc., AstraZeneca plc, Genentech, Inc. and Johnson & Johnson.

We conduct direct sales in the United States, the United Kingdom, Germany, France, Spain, Sweden and Canada. We sell primarily through distributors in other countries. Aggregate sales to our largest customer, GE Healthcare, a distributor with end-users similar to ours, accounted for approximately 6% of our revenues for the years ended December 31, 2012 and 2011. We have several thousand customers worldwide and no other customer accounted for more than 5% of our revenues for such periods. Our September 2009 acquisition of Denville expanded our U.S. field sales capabilities and provided direct access to the laboratory consumables market.

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Sales and Marketing

For the year ended December 31, 2012, revenues from direct sales to end-users represented approximately 57% of our revenues; and revenues from sales of our products through distributors represented approximately 43% of our revenues.

Direct Sales

We periodically produce and mail a Harvard Apparatus full-line catalog, which contains approximately 11,000 products on 850 pages and is printed in varying quantities ranging from 50,000 to 100,000 copies. The latest catalog, which is accessible on our website, serves as the primary sales tool for the Harvard Apparatus product line, which includes both proprietary manufactured products and complementary products from various suppliers. Our reputation as a leading producer in many of our manufactured products creates traffic to the catalog and website, enables cross-selling and facilitates the introduction of new products. In addition to the comprehensive catalog, we create and mail abridged catalogs that focus on specific product areas along with direct mailers and targeted e-mailers, which introduce or promote new products. We distribute the majority of our catalog products through our worldwide subsidiaries.

We have field sales forces in several of our LSRT markets, where our sales people visit our customers laboratories each day. We have field sales teams in the United States, Canada, the United Kingdom, Germany, France and Spain.

In those regions where we do not have a subsidiary, or for products which we have acquired that had distributors in place at the time of our acquisition, we use distributors.

Distributors

GE Healthcare is our largest distributor, accounting for 6%, 6% and 10% of our revenues for the years ended December 31, 2012, 2011 and 2010, respectively.

Historically, GE Healthcare has been our primary distributor, marketer and seller of a significant portion of our spectrophotometer and DNA/RNA calculator product lines of our Biochrom subsidiary. In April 2008, our Biochrom subsidiary entered into a new distribution agreement with GE Healthcare. Under the terms of the agreement, GE Healthcare serves as the exclusive, worldwide (except Canada) distributor, marketer and seller of a significant portion of the spectrophotometer and DNA/RNA calculator product lines sold by Biochrom, including a microliter spectrophotometer to which GE Healthcare has exclusive access on a worldwide basis including Canada. The term of the agreement expires December 31, 2013. It may be terminated by either party upon one year advance written notice and may be extended by GE Healthcare for additional one-year periods. Additionally, upon breach of certain terms of the agreement by either party, the agreement may be terminated with a 60-day notice period.

In November 2003, in connection with the acquisition of Hoefer from GE Healthcare, we entered into a separate distribution agreement with GE Healthcare for the distribution of the Hoefer products. This contract had a five year term with an automatic five-year renewal period, provides for minimum purchases for the first three years, allows us to use the Hoefer name (which we acquired in the transaction) on direct sales by us to end users or through other distributors, and may be terminated after five years with a one year advance notice upon certain circumstances. Additionally, upon breach of certain terms of the agreement, such as pricing, exclusivity and delivery, by either party, the agreement may be terminated with a 30-day notice period. The current contract ends on September 30, 2013. We are currently in discussions with GE Healthcare regarding the extension of the contact.

In addition to engaging GE Healthcare as the primary distributor for our Biochrom and Hoefer products, we also engage distributors for the sales of Harvard Apparatus, Warner, BTX, KD Scientific, Asys Hitech, Anthos, Panlab, Coulbourn, CMA and SciePlas branded products in certain areas of the world and for certain product lines.

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Backlog

Our order backlog was approximately $4.5 million and $5.0 million as of December 31, 2012 and 2011, respectively. We include in backlog only those orders for which we have received valid purchase orders. Purchase orders may be cancelled at any time prior to shipment. Our backlog as of any particular date may not be representative of actual sales for any succeeding period. We typically ship our backlog at any given time within 90 days.

Research and Development

Our principal research and development mission in our LSRT business is to develop products that address growth opportunities within the life science research process, particularly for application in the areas of ADMET testing and molecular biology and liquid handling. Through our RMD division, we are also working to develop new products aimed at long term opportunities in the emerging field of regenerative medicine.

Our research and development expenses were approximately $7.3 million, $5.4 million and $4.7 million in 2012, 2011 and 2010, respectively. The increase in research and development expenses during 2012 was primarily due to increased spending in our RMD division. We anticipate that we will continue to make investments in research and development activities as we deem appropriate given the circumstances at such time. We plan to continue to pursue a balanced development portfolio strategy of originating new products from internal research and acquiring products through business and technology acquisitions.

We maintain development staff in most of our manufacturing facilities to design and develop new products and to re-engineer existing products to bring them to the next generation level. Our in-house development is focused on our current technologies.

Manufacturing

We manufacture and test the majority of our products in our principal manufacturing facilities located in the United States, the United Kingdom, Sweden, Spain and Germany. We have considerable manufacturing flexibility at our various facilities, and each facility can manufacture multiple products at the same time. We maintain in-house manufacturing expertise, technologies and resources. We seek to maintain multiple suppliers for key components that are not manufactured in-house, and while some of our products are dependent on sole-source suppliers, we do not believe our dependence upon these suppliers creates any significant risks.

Our manufacturing operations primarily involve assembly and testing activities along with some machine based processes. We manufacture syringe pumps, ventilators, cell injectors, molecular sample preparation products and electroporation products in Holliston, Massachusetts. The manufacture of our cell biology and electrophysiology products takes place in both our Holliston, Massachusetts facility and our Hamden, Connecticut facility. We manufacture spectrophotometers, amino acid analysis systems, low-volume, high-throughput liquid dispensers and our plate readers in our Cambridge, England facility. We manufacture our surgery and anesthesia related products and physiology-teaching products in our Edenbridge, England facility. We manufacture our complete organ testing systems and bioreactors in March-Hugstetten, Germany and Holliston, Massachusetts. Our electrophoresis products are manufactured at our Richmond, California facility. Behavioral science products are manufactured in our Barcelona, Spain and Whitehall, Pennsylvania facilities. Our microdialysis products are manufactured at our Holliston, Massachusetts and Solna, Sweden facilities. We manufacture our pipette products in our Nordhausen, Germany facility. Our synthetic scaffold manufacturing takes place in Holliston, Massachusetts.

Competition

The markets into which we sell our products are highly competitive, and we expect the intensity of competition to continue or increase. We compete with many companies engaged in developing and selling tools for life science research and regenerative medicine. Many of our competitors have greater financial, operational, sales and marketing resources, and more experience in research and development and commercialization than we

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have. Moreover, our competitors may have greater name recognition than we do, and many offer discounts as a competitive tactic. These competitors and other companies may have developed or could in the future develop new technologies that compete with our products, which could render our products obsolete. We cannot assure you that we will be able to make the enhancements to our technologies necessary to compete successfully with newly emerging technologies. We are not aware of any significant products sold by us as being currently obsolete.

We believe that we offer one of the broadest selections of products to organizations engaged in life science research and regenerative medicine. We are not aware of any competitor that offers a product line of comparable breadth across our target markets. We have numerous competitors on a product line basis. We believe that we compete favorably with our competitors on the basis of product performance, including quality, reliability and speed, technical support, price and delivery time.

We compete with several companies that provide instruments for ADMET testing and molecular biology. In the ADMET testing area, we compete with, among others, Amaxa GmbH, Becton, Dickinson and Company, Eppendorf AG, Kent Scientific Corporation, Razel Scientific Instruments, Inc. and Ugo Basile. In the molecular biology products area, we compete with, among others, Danaher Corporation, Bio-Rad Laboratories, Inc., Eppendorf AG, Life Technologies Corporation, MDS Analytical Technologies, PerkinElmer, Inc. and Thermo Fisher Scientific Inc. For RMD, we are not aware of any companies whose products are directly competitive with our bioreactor and scaffold system. However, in our key markets we may in the future compete with multiple pharmaceutical, biotechnology, medical device and scientific research instrument companies, including, among others, Aastrom Biosciences, Aldagen, BioTime, Baxter International, Inc., Bose Corporation, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Genzyme (acquired by Sanofiaventis), Harvest Technologies, Mesoblast, Nanofiber Solutions, Organovo, Osiris Therapeutics, Tengion, Tissue Genesis, Inc., Tissue Growth Technologies, Transmedics, United Therapeutics and W.L. Gore and Associates. We are not aware of any companies whose products are directly competitive with our clinical infusion pumps for cell injection. However, with respect to our clinical infusion pump for hospital drug infusion applications, we will compete with Baxter International, Inc., Fresenius Medical Care, Smiths Medical, and B. Braun Melsungen, among others.

Many of our potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot forecast if or when these or other companies may develop competitive products. We expect that other products will compete with products and potential products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage.

Seasonality

Our business is generally not seasonal, however, sales and earnings in our third quarter are usually flat or down from the second quarter primarily because there are a large number of holidays and vacations during such quarter, especially in Europe. Our fourth quarter sales and earnings are often the highest in any fiscal year compared to the other three quarters, primarily because many of our customers tend to spend budgeted money before their own fiscal year ends. However in 2012, concerns over government spending levels caused our fourth quarter revenues to be less than the first and second quarter revenues.

Intellectual Property

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade-secret laws, as well as confidentiality provisions in our contracts. Patents or patent applications cover certain of our new technologies. Most of our more mature product lines are protected by trade names and trade secrets only.

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We have implemented a patent strategy designed to provide us with freedom to operate and facilitate commercialization of our current and future products. Our success depends to a significant degree upon our ability to develop proprietary products and technologies. We intend to continue to file patent applications as we develop new products and technologies. Since 2010, we have filed thirteen provisional patents and patents in the field of regenerative medicine, covering over 400 claims for our products and their functions.

Patents provide some degree of protection for our intellectual property. However, the assertion of patent protection involves complex legal and factual determinations and is therefore uncertain. The scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us may be successfully challenged, invalidated, circumvented or unenforceable so that our patent rights would not create an effective competitive barrier. Moreover, the laws of some foreign countries may protect our proprietary rights to a greater or lesser extent than the laws of the United States. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in areas of interest to us. As a result, there can be no assurance that patents will be issued from any of our patent applications or from applications licensed to us. As a result of these factors, our intellectual property positions bear some degree of uncertainty.

We also rely in part on trade-secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in patents and copyrights arising from their work for us. Although many of our U.S. employees have signed agreements not to compete unfairly with us during their employment and after termination of their employment, through the misuse of confidential information, soliciting employees, soliciting customers and the like, the enforceability of these provisions varies from jurisdiction to jurisdiction and, in some circumstances, they may not be enforceable. In addition, it is possible that these agreements may be breached or invalidated and if so, there may not be an adequate corrective remedy available. Despite the measures we have taken to protect our intellectual property, we cannot assure you that third parties will not independently discover or invent competing technologies, or reverse engineer our trade secrets or other technologies. Therefore, the measures we are taking to protect our proprietary rights may not be adequate.

We do not believe that our products infringe on the intellectual property rights of any third party. We cannot assure you, however, that third parties will not claim such infringement by us or our licensors with respect to current or future products. We expect that product developers in our market will increasingly be subject to such claims as the number of products and competitors in our market segment grows and the product functionality in different market segments overlaps. In addition, patents on production and business methods are becoming more common and we expect that more patents will be issued in our technical field. Any such claims, with or without merit, could be time-consuming, result in costly litigation and diversion of management s attention and resources, cause product shipment delays or require us to enter into royalty or licensing agreements. Moreover, such royalty or licensing agreements, if required, may not be on terms advantageous to us, or acceptable at all, which could seriously harm our business or financial condition.

Harvard is a registered trademark of Harvard University. The marks Harvard Apparatus and Harvard Bioscience are being used pursuant to a license agreement entered into in December 2002 between us and Harvard University.

Government Regulation

We are not subject to direct governmental regulation other than the laws and regulations generally applicable to businesses in the domestic and foreign jurisdictions in which we operate. In particular, our current LSRT products are not subject to pre-market approval by the FDA for use on human clinical patients. As we continue to develop new products for regenerative medicine applications in our RMD division, we expect that we will seek approvals from the FDA and EU for certain such products for use in clinical applications. We expect the first such application to be for a clinical syringe pump which will be the platform for cell injector products. We plan to file applications with the FDA, EU and other regulatory agencies for the clinical syringe pump in 2013. In addition, we believe we are currently in compliance with all relevant environmental laws.

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Employees

As of December 31, 2012, we employed 422 employees, of which 398 are full-time and 24 are part-time. Geographical residence information for these employees is summarized in the table below:

	As of December 31, 2012
United States	230
United Kingdom	91
Spain	32
Germany	48
Sweden	10
Canada	8
France	3
Total	422

We believe that our relationship with our employees is good. None of our employees is subject to any collective bargaining agreement.

Discontinued Operations

In November 2007, we completed the sale of the assets of our Genomic Solutions Division and the stock of our Belgian subsidiary, MAIA Scientific, both of which were part of our Capital Equipment Business Segment, to Digilab, Inc. The purchase price paid by Digilab under the terms of the Asset Purchase Agreement consisted of $1.0 million in cash plus additional consideration in the form of an earn-out based on 20% of the revenue generated by the acquired business as it was conducted by Digilab over a three-year period post-transaction. Earn-out amounts were evidenced by interest bearing promissory notes which were due on November 30, 2012. The unpaid principal balance of the promissory notes had an interest of LIBOR plus 1100 basis points per annum. Digilab had delivered promissory notes of $4.6 million. To date we have recorded valuation allowances for 100% of the earn-out promissory notes as we have deemed their collectability as being uncertain.

In September 2008, we completed the sale of assets of our Union Biometrica Division including our German subsidiary, Union Biometrica GmbH, representing at that time the remaining portion of our Capital Equipment Business Segment, to UBIO Acquisition Company. The purchase price paid by UBIO Acquisition Company under the terms of the asset purchase agreement consisted of $1 in cash, the assumption of certain liabilities, plus additional consideration in the form of an earn-out based on the revenue generated by the acquired business as it is conducted by UBIO Acquisition Company over a five-year post-transaction period in an amount equal to (i) 5% of the revenue generated up to and including $6.0 million each year and (ii) 8% of the revenue generated above $6.0 million each year. Any earn-out amounts are evidenced by interest-bearing promissory notes due on September 30, 2013 or at an earlier date based on certain triggering events. We regularly monitor the financial performance of the UBIO Acquisition Company to determine their ability to pay the earn out amounts when they become due on September 30, 2013 or at an earlier date based on certain triggering events. As at December 31, 2012, UBIO Acquisition Company had delivered promissory notes of $1.1 million. The unpaid principal balance of the promissory notes bear an interest of 12% per annum. Prior to the fourth quarter of 2012, we recorded valuation allowances for 100% of the earn-out promissory notes as we have deemed their collectability as being uncertain. During the fourth quarter of 2012, we determined that the realization was probable. Therefore we made a decision to reverse the valuation allowance and recognize the earn-out amount and the interest thereon of approximately $0.8 million in our statements of income under Income from discontinued operations, net of tax .

Geographic Area

Financial information regarding geographic areas in which we operate is provided in Note 17 of the Notes to Consolidated Financial Statements, which are included elsewhere in this report.

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Executive Officers of the Registrant

The following table shows information about our executive officers as of December 31, 2012.

Name	Age	Position
Chane Graziano	74	Chief Executive Officer and Chairman of the Board of Directors
David Green	48	President and Director
Thomas McNaughton	52	Chief Financial Officer and Treasurer
Susan Luscinski	56	Chief Operating Officer

Chane Graziano has served as the Company s Chief Executive Officer and Chairman of the Board of Directors of the Company since March 1996. Prior to joining the Company, Mr. Graziano served as the President of Analytical Technology Inc., an analytical electrochemistry instruments company, from 1993 to 1996 and as the President and Chief Executive Officer of its predecessor, Analytical Technology Inc.-Orion, an electrochemistry instruments and laboratory products company, from 1990 until 1993. Mr. Graziano served as the President of Waters Corporation, an analytical instrument manufacturer, from 1985 until 1989. Mr. Graziano has over 46 years experience in the laboratory products and analytical instruments industry. Mr. Graziano serves on the Board of Directors of Nova Holdings LLC and certain of its subsidiaries, including Nova Ventures Corporation, and Advion BioSciences, Inc.

David Green has served as the Company s President and a member of the Board of Directors of the Company since March 1996. Prior to joining the Company, Mr. Green was a strategy consultant with Monitor Company, a strategy consulting company, in Cambridge, Massachusetts and Johannesburg, South Africa from June 1991 until September 1995 and a brand manager for household products with Unilever PLC, a packaged consumer goods company, in London from September 1985 to February 1989. Mr. Green currently is President and a board member of the Harvard Business School Healthcare Industry Alumni Association, and on the Executive Advisory Board of The University of Massachusetts Lowell Nanomanufacturing Center. Mr. Green graduated from Oxford University with a B.A. Honors degree in physics and holds a M.B.A. degree with distinction from Harvard Business School.

Thomas McNaughton has served as our Chief Financial Officer and Treasurer since November 14, 2008. Prior to joining Harvard Bioscience, Mr. McNaughton provided, from January 2008 to September 2008 financial consulting services, primarily to an angel-investing group and a silicon manufacturing start-up. From 2005 to 2007, Mr. McNaughton served as Vice President Finance and Chief Financial Officer for Tivoli Audio, LLC, a venture capital-backed global manufacturer of premium audio systems. Prior to joining Tivoli Audio, LLC, from 1990 to 2005, Mr. McNaughton served in various managerial positions in the areas of financial reporting, treasury, investor relations, and acquisitions within Cabot Corporation, a global manufacturer of fine particulate products, and served from 2002 to 2005 as Finance Director, Chief Financial Officer of Cabot Supermetals, a $350 million Cabot division that provided high purity tantalum and niobium products to the electronics and semiconductor industries. Mr. McNaughton practiced from 1982 to 1990 as a Certified Public Accountant in the audit services group of Deloitte & Touche, LLP. Mr. McNaughton holds a B.S. in accounting and finance from Babson College.

Susan Luscinski has served as our Chief Operating Officer since August 2004 and served as our Principal Accounting Officer from May 2008 through November 2008. Ms. Luscinski served as our Chief Financial Officer from August 2001 until August 2004 and Vice President of Finance and Administration from May 1999 until August 2001. Ms. Luscinski served as our Corporate Controller from May 1988 until May 1999 and has served in various other positions at our Company and its predecessor since January 1985.

Available Information and Website

Our website address is www.harvardbioscience.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and exhibits and amendments to those reports filed or furnished with the Securities and Exchange Commission pursuant to Section 13(a) of the Exchange Act are available for review on our website and the Securities and Exchange Commission s website at www.sec.gov. Any such

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materials that we file with, or furnish to, the SEC in the future will be available on our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. ***Risk Factors.***

As previously discussed, our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur our business operations, performance and financial condition could be adversely affected and the trading price of our common stock could decline. These risk factors should be read in conjunction with the other information in this Annual Report on Form 10-K.

The current soft economic environment and continued uncertainty in the financial markets and other adverse changes in general conditions may exacerbate certain risks affecting our business.

The global financial crisis that began in 2008 caused disruption in the financial markets, including somewhat diminished liquidity and credit availability. We are unable to predict the strength and duration of an economic recovery. During 2012 and continuing to today research customers in our major markets have been concerned about levels of future government spending. In the U.S., researchers appear concerned about the effects of the sequestration on the federal government s future funding levels for life science research. While these conditions have not impaired our ability to access credit markets to date, there can be no assurance that these conditions will not adversely affect our ability to do so in the future, particularly if there is further deterioration in the world financial markets and major economies.

As our business has grown, we have become increasingly subject to the risks arising from adverse changes in domestic and global economic conditions. Continued concerns about credit markets, consumer confidence, economic conditions, government spending to sponsor life science research, volatile corporate profits and reduced capital spending could continue to negatively impact demand for our products. If economic growth in the U.S. and other countries continues to be slow and does not improve, customers may delay purchases of our products. The tightening of credit in financial markets may adversely affect the ability of our customers and suppliers to obtain financing, which could result in a decrease in, or deferrals or cancellations of, the sale of our products. If global economic and market conditions, or economic conditions in the United States, remain uncertain or persist, spread, or deteriorate further, we may experience a material adverse effect on our business, operating results and financial condition. Unstable economic, political and social conditions make it difficult for our customers, our suppliers and us to accurately forecast and plan future business activities. If such conditions persist, our business, financial condition and results of operations could suffer. We cannot project the extent of the impact of the economic environment on our industry or us.

Many of our customers, including universities, government research laboratories, private foundations and other institutions, obtain funding for the purchase of products from grants by governments or government agencies. A potential decrease in the level of governmental spending allocated to scientific and medical research could substantially reduce or even eliminate these grants. If government funding necessary to purchase our products were to decrease, our business and results of operations could be materially adversely affected.

Our revenues will likely be affected by various factors, including the timing of purchases by customers and the seasonal nature of purchasing in Europe.

Our revenues will likely be affected by various factors, including the seasonal nature of purchasing in Europe. Our revenues may vary from quarter to quarter due to a number of factors, including the timing of catalog mailings and new product introductions, the release of grant and budget funding, future acquisitions and our substantial sales to European customers, who in summer months often defer purchases. In particular, delays or reduction in purchase orders from the pharmaceutical and biotechnology industries could have a material adverse effect on us and could adversely affect our stock price.

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Attractive acquisition opportunities may not be available to us in the future.

We will consider the acquisition of other businesses. However, we may not have the opportunity to make suitable acquisitions on favorable terms in the future, which could negatively impact the growth of our business. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. We expect that our competitors, many of which have significantly greater resources than we do, will compete with us to acquire compatible busi