INTEGRA LIFESCIENCES HOLDINGS CORP
Form 10-K
February 26, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

or

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 NO. 0-26224

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	51-0317849
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)
311 ENTERPRISE DRIVE PLAINSBORO, NEW JERSEY	08536
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	(ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (609) 275-0500
SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, Par Value $.01 Per Share	The Nasdaq Stock Market LLC

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 x No o

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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. x

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

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

As of June 30, 2015, the aggregate market value of the registrant’s common stock held by non-affiliates was approximately $1,741.0 million based upon the closing sales price of the registrant’s common stock on The Nasdaq Global Market on such date. The number of shares of the registrant’s Common Stock, $0.01 par value, outstanding as of February 23, 2016 was 37,000,721.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant’s definitive proxy statement relating to its scheduled May 24, 2016 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

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PART I

ITEM 1. BUSINESS

OVERVIEW

The terms “we,” “our,” “us,” “Company” and “Integra” refer to Integra LifeSciences Holdings Corporation, a Delaware corporation, and its subsidiaries, unless the context suggests otherwise.

Integra, headquartered in Plainsboro, New Jersey, is a world leader in medical technology. The Company employs approximately 3,500 people around the world who are dedicated to limiting uncertainty for surgeons, so that they can concentrate on providing the best care for their patients. Integra offers innovative solutions, including leading regenerative technologies, specialty surgical solutions, and orthopedic solutions. Revenues grew to $882.7 million in 2015, an increase of 11% from $796.7 million in 2014.

Integra was founded on an engineered collagen technology platform that can be used to repair and regenerate tissue. The Company has developed numerous product lines from this technology for applications ranging from burn and deep tissue wounds to repair of dura mater in the brain to repair of nerve and tendon. Over the past 25 years, Integra has grown by building upon this core regenerative technology, acquiring businesses in markets with overlapping customer bases, and developing products to further meet the needs of our target customers.

On July 1, 2015, the Company completed the separation of SeaSpine Holdings Corporation ("SeaSpine") from Integra through the pro rata distribution of 100% of the common stock of SeaSpine to Integra's stockholders of record as of the close of business on June 19, 2015. Each Integra shareholder received one share of SeaSpine common stock for every three shares of Integra common stock held as of the record date. As a result, SeaSpine became an independent, publicly traded company listed on the NASDAQ market, and Integra retains no ownership interest in SeaSpine. The distribution was structured to be tax-free to Integra and its shareholders for U.S. federal income tax purposes.

VISION

We aspire to be a multi-billion dollar diversified global medical technology company that helps patients by limiting uncertainty for healthcare professionals. Our customers will recognize us as a leader in specialty surgical applications, regenerative technologies and extremities orthopedics worldwide.

STRATEGY

Our strategy is built around three pillars - execute, optimize, and accelerate growth. These three pillars support our strategic initiatives to deliver on our commitments through improved planning and communication, optimize our infrastructure, and grow our revenues by introducing new products to the market through internal development, geographic expansion, and strategic acquisitions.

This is an essential strategic approach for two reasons. First, the costs inherent in operating a medical technology company have increased at an accelerating rate in recent years and continue to rise. Scale is therefore correlated with rates of profitability in our industry. Our strategic response is to focus efforts and investments on accelerating growth in the clinical areas where we compete today. Second, we compete in a complex and highly regulated industry, and we have grown through more than 45 acquisitions in our history. We have made significant accomplishments in the past several years to reduce our operational footprint, simplify our organizational structure and build platforms for common systems. To effectively execute on our plans to grow our core business and integrate acquisitions, we must continue to improve our infrastructure and processes. These improvements will create a solid platform with operational stability from which to grow our business.

To that end, our executive leadership team has set forth several near-term objectives aligned to this strategy:

Portfolio Optimization. We are investing in innovative product development to drive a multi-generational pipeline for our key product franchises. Under the leadership of our Chief Scientific Officer, our product development efforts focus on regenerative technologies and other projects with the potential for significant returns on investment. We have a stated goal of generating at least one quarter of our organic growth in any one year from products launched in the last two to three years. These recent efforts have contributed to an active schedule of impactful product launches for 2016 through 2018. In addition to new product development, we are funding studies to gather clinical evidence to support successful launches and improved reimbursement for existing products. We also continue to identify low-growth, low-margin products and product franchises for discontinuation and will continue to look at other ways of optimizing our portfolio.

International Expansion. We generate less than one quarter of our revenues from markets outside the United States, whereas most large medical technology companies produce significantly more of their revenues internationally. Therefore, we see an opportunity to accelerate revenue growth by increasing our international presence. In order to achieve this, we are expanding

our commercial infrastructure in key markets, and securing ownership or other control of our product registrations and distribution system. Additionally, we have a plan for registering and launching our existing products in countries where we already have a selling presence, but are missing key leading brands. We expect the commercial focus on key markets and products that carry both high margins and relevant price points to increase our proportion of international business.

Commercial Channel Optimization. Through the recent acquisition of TEI Biosciences, Inc. and TEI Medical Inc. (collectively "TEI") in July 2015 and the planned launch of Omnigraft™ for diabetic foot ulcers in mid-2016, we have established a new presence in the outpatient segment of the fast-growing advanced wound care market. We are building up this commercial channel and support infrastructure to facilitate the Omnigraft product launch. Our new 3x3 strategy will take advantage of our unique position to call upon providers through three sales channels (inpatient, outpatient, and multi-center enterprise-wide contracting) and offer three product families for advanced wound healing (engineered collagen, acellular collagen and human amniotic wound dressings). More broadly, to compete successfully against much larger, diversified medical technology competitors, we are building upon our leadership brands across our product franchises and engaging hospital system customers through enterprise-wide contracts.

Infrastructure Optimization. Over the past four years, we have reduced the number of manufacturing and distribution facilities that we operate by nine and have largely completed plans to consolidate operational activities into existing sites with greater utilization and efficiency. We have expanded our collagen manufacturing capabilities. In addition, we have a centrally led strategic sourcing and procurement effort, which has lowered our direct costs for certain purchased goods. These changes continue to control costs and enable higher marginal profit and cash flow. We have also completed the majority of a common enterprise resource planning ("ERP") system implementation. Approximately 85% of our revenue operates on a single system. We plan to complete these implementation activities in 2016. With these changes and the simplification of our operational structure during 2015 to two global business segments, we have the systems and structure in place to support a much larger business, which will enable us to better leverage our expenditures on general and administrative items over the next several years.

Strategic Corporate Development. Over the years, we have successfully acquired and in-licensed businesses, products and technologies to grow our business. Our corporate development program is a core competency, and an important part of our strategy is to continue to pursue strategic transactions and licensing agreements to increase relevant scale in the clinical areas in which we compete. Heading into 2016, identifying additional opportunities and integrating the TEI and Salto Talaris® acquisitions will be key objectives for the company. Acquisitions, in particular, may expand international distribution, add a technology platform, increase the scale of one of our current portfolios, or provide access into an adjacent growth area that leverages the sales channel. We focus our efforts on the clinical areas of would care, extremities orthopedics, and specialty surgical applications. Our corporate development capabilities are increasingly important to remain competitive in today's environment.

Finally, we are investing in training programs to develop our leadership deeper in the organization and will be investing in targeted additions to our sales organization to improve market coverage. These initiatives, investments, and talent development efforts will strengthen the foundation necessary to support a faster growing, multi-billion dollar global medical technology company. Our strategy to execute, optimize and accelerate growth will enable us to continue to be a company that helps limit uncertainty for customers and touches millions of patients each year, while driving returns for shareholders.

BUSINESS SEGMENTS

In the first quarter of 2015, we began to disclose three global reportable segments as a result of changes in how we internally manage and report the results of our businesses. Following the spin-off of SeaSpine, we currently manufacture and sell our products in the following two global reportable business segments: Specialty Surgical Solutions, and Orthopedics and Tissue Technologies. We included financial information regarding our reportable business segments and certain geographic information under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and in Note 15, Segment and Geographic Information to our consolidated financial statements.

Specialty Surgical Solutions

Our Specialty Surgical Solutions business offers specialty surgical instrumentation for a broad range of specialties, including a market-leading product portfolio used in the neurosurgery operating suite and critical care unit.

We sell products and solutions for dural repair, precision tools and instruments, tissue ablation, and neuro critical care. For neurosurgeons, we have products for each step of a procedure and the care of the patient after surgery, from both equipment and implants used in the neurosurgery operating room to monitoring in the neurosurgery intensive care unit. We are also among the largest surgical instrument suppliers in the United States to hospitals, acute care surgical centers, and clinician

offices. Our portfolio includes over 60,000 instrument patterns and surgical products, surgical headlight systems and table-mounted retractors that address a broad set of surgical specialties.

In the United States, Specialty Surgical Solutions products are sold through a combination of directly employed sales representatives, sales agents and distributors, depending on the customer call point. We have a specialized sales organization composed of directly employed sales representatives who primarily call on neurosurgeons and the neuro critical care unit. In addition, we have a sales organization consisting of a combination of directly employed sales representatives and sales agents who primarily call on the central sterile processing unit of hospitals and acute care surgical centers. Finally, we reach the diverse alternate site call point, which includes physician, dental and veterinary offices, through distributors. Internationally, we sell certain products and product lines from the Specialty Surgical Solutions portfolio through a combination of direct efforts, primarily in certain European countries, Australia, New Zealand, and Canada, and through distributors in other countries.

Orthopedics and Tissue Technologies

Our Orthopedics and Tissue Technologies business offers a unique combination of differentiated soft tissue repair and tissue regeneration products, and small bone fixation and joint replacement solutions.

We sell regenerative technology products that can be used to provide treatment for acute and chronic wounds, surgical tissue repair including hernia repair, peripheral nerve repair and protection, and tendon repair. For extremity bone and joint reconstruction procedures, we sell hardware products, such as bone and joint fixation and joint replacement devices, implants and instruments, which provide for the orthopedic reconstruction of bone in the hand, wrist, elbow and shoulder (Upper Extremity), and the foot, ankle and leg below the knee (Lower Extremity).

In the United States, we have a specialized sales organization composed of directly employed sales representatives, as well as specialty distributors, organized based upon their call point. A team of extremities sales representatives call on surgeons who treat acute wounds in hospitals, extremity orthopedic disorders, including osteoarthritis, rheumatoid arthritis, wrist, ankle and shoulder arthroplasty, and other conditions requiring foot or hand reconstruction. In addition, we sell our shoulder products through a specialty distributor network of sales agents who call on shoulder surgeons. A team of wound care clinic sales representatives call on physicians who treat chronic wounds in the outpatient wound care clinic setting. A team of surgical sales representatives call on surgeons who treat patients requiring surgical tissue repair and reconstruction. Finally, we have a small group of clinical sales specialists who focus on our regenerative products and support these three sales organizations, extremities, wound care and surgical, to address their clinicians' needs as they relate to this class of products. Outside the United States, we have a small direct sales presence, primarily in certain European countries, Australia, New Zealand, and Canada, and utilize distributors in other international markets to sell certain products and product lines from the Orthopedics and Tissue Technologies portfolio.

This segment also includes private-label sales of a broad set of our regenerative technologies. Our customers are other medical technology companies that sell to end markets primarily in orthopedics, surgical and wound care.

PRODUCTS - OVERVIEW

We offer thousands of products for the medical specialties we target. Our objective is to develop, acquire or otherwise provide products that will limit uncertainty for hospitals and surgeons. These products include our regenerative technology implants, metal implants, instruments and equipment for small bone orthopedic surgery and specialty surgical applications. We distinguish ourselves by emphasizing the importance of regenerative technology, which we define as surgical implants derived from our proprietary collagen matrix technology and other biologic platforms that enable or facilitate the body's healing process and are resorbed.

RESEARCH AND DEVELOPMENT STRATEGY

Our research and development activities focus on identifying unmet surgical needs and addressing those needs with innovative solutions and products. We apply our core competency in regenerative technology to products for

neurosurgical, orthopedic and wound applications, and we have extensive programs in the core platform technologies of orthopedic hardware and electromechanical technologies. In addition to our activities aimed at acquiring or in-licensing new products, we are optimizing our current portfolio through product franchise review and rationalization. We are focusing our development efforts on innovative products with an emphasis on product efficacy and clinical evidence.

Regenerative Technologies. Because implants derived from our regenerative technology platform represent a fast-growing, high-margin opportunity for us, we allocate a large portion of our research and development budget to these projects. Our

regenerative technology development program applies our expertise in bioengineering a range of biomaterials including natural collagen and human tissues as well as synthetics such as polymers. The unique product designs are used for neurosurgical and orthopedic surgery applications, as well as dermal regeneration, tendon and nerve repair, and chronic and acute wounds. In 2015, Integra reported the results of a multi-center, randomized, controlled clinical trial under the United States Food and Drug Administration ("FDA") Investigational Device Exemption ("IDE") comparing the safety and effectiveness of INTEGRA® Dermal Regeneration Template to the standard of care for the treatment of diabetic foot ulcers. The data from this trial formed the foundation for the Premarket Approval ("PMA") Supplement application that we filed with the FDA. The FDA approved the PMA on January 7, 2016, and the Company anticipates commercializing the resulting Diabetic Foot Ulcer ("DFU") product, Omnigraft, in mid-2016. We are also investing in next generation nerve products, additional clinical studies for indications to support existing products including for an indication in ankle arthroplasty, and longer-term research programs to evaluate combination products.

Orthopedic Hardware. We develop fixation devices and other implants and instruments for upper and lower extremities to both provide next generation solutions and expand our product portfolio. This portfolio focuses on joint replacement products. Integra already has a strong shoulder portfolio, which includes a total shoulder system and a reverse shoulder. We are in the final stages of development for a glenoid replacement product and are developing a pyrocarbon hemi-shoulder product to add to that portfolio. We have a strong differentiated asset that resides in our exclusively licensed pyrocarbon products, and we continue to invest to bring new products to market with this technology, which has shown significantly less wear on bone then traditional metals. Our Cadence total ankle replacement product is also in the final stages of development before a controlled market release, and will complement the recently acquired Salto Talaris® ankle. The Cadence ankle is designed to simplify the ankle replacement procedure and maximize reproducibility through its instrumentation and technique.

Electromechanical Technologies and Instrumentation. Because our electromechanical products and instruments represent products that limit uncertainty for our surgeon customers, we continue to invest in approvals for new indications and next generation improvements to our market-leading products. We are developing the next generation tissue ablation system enhancements, which are in late stages of development. We are focusing on ease of set-up, ensuring that the CUSA® enhancements have a user-friendly interface and hand pieces that are ergonomic, a key request of surgeons. We also work with a number of primarily German instrument partners to bring new surgical instrument patterns to the market, enabling us to add new instruments with minimal expense. Finally, our lighting franchise is among the most dynamic, and we continue to invest in ongoing development in LED technology.

COMPETITION

Our primary competitors in specialty surgical solutions are the Aesculap division of B. Braun Medical, Inc., Johnson & Johnson, Medtronic, Inc., Stryker Corporation, Becton, Dickinson and Company, and C.R. Bard, Inc. In addition, we compete with many smaller specialized companies and larger companies that do not otherwise focus on specialty surgical solutions. We rely on the depth and breadth of our sales and marketing organization, our innovative technology, and our procurement operation to maintain our competitive position in much of our precision tools and instruments portfolio.

Our competition in orthopedics and tissue technologies includes the DePuy/Synthes business of Johnson & Johnson, Stryker Corporation, Wright Medical Group, N.V., Smith & Nephew plc, MiMedx Group, Inc., Acelity L.P. Inc., and Zimmer Biomet Holdings, Inc., as well as other major orthopedic companies that carry a full line of small bone and joint fixation and soft tissue products.

Finally, in certain cases our products compete primarily against medical practices that treat a condition without using a medical device or any particular product, such as medical practices that utilize autograft tissue instead of our dermal regeneration products, duraplasty products and nerve repair products. Depending on the product line, we compete on the basis of our products' features, strength of our sales force or distributors, sophistication of our technology and cost effectiveness of our solution.

GOVERNMENT REGULATION

We are a manufacturer and marketer of medical devices, and therefore are subject to extensive regulation by the FDA, the Center for Medicare Services of the U.S. Department of Health and Human Services, other federal governmental

agencies and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices, and other matters.

United States Food and Drug Administration

The FDA inspected our Añasco, Puerto Rico facility in October and November 2012, and issued a warning letter for that facility on February 13, 2013. On November 26, 2013, the FDA completed its second inspection of the Añasco facility and issued a new Form 483 with six additional observations. On September 30, 2014, the FDA completed its third inspection of the Añasco facility, concluded that the Company had addressed the issues raised in the Warning Letter and previous inspectional observations, and issued no other inspectional observations. The Añasco warning letter was closed out effective January 14, 2015, because the FDA concluded that the Company had addressed the issues raised in the warning letter and previous inspectional observations.

We have an outstanding FDA warning letter related to TEI Biosciences Inc., a recent acquisition by Integra on July 17, 2015. TEI Biosciences Inc. received a Warning Letter from the FDA dated May 29, 2015 for promoting the product SurgiMend for breast surgery applications that were not cleared in the 510(k) process and do not have a PMA Approval for the indication. The FDA requested that TEI Biosciences Inc. immediately cease all activities that resulted in misbranding or adulteration of the product in commercial distribution. The FDA also required TEI Biosciences Inc. to cease all violations regarding promotion of the product for an indication that it was not cleared or approved. TEI Biosciences Inc. responded with a corrective action plan to the FDA and took action to address the issues prior to the completion of the acquisition. We will continue to monitor this activity and address all corrective actions submitted to the FDA. The FDA may not accept our corrective action plan or it may choose to scrutinize other promotional claims on products and require additional corrective actions. We do not expect to incur material operating expenses to complete the corrective action plan.

The regulatory process of obtaining product approvals and clearances can be onerous and costly. The FDA requires, as a condition to marketing a medical device in the United States, that we secure a Premarket Notification clearance pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (the “FD&C Act”) or an approved PMA application (or supplemental PMA application). Obtaining these approvals and clearances can take up to several years and may involve preclinical studies and clinical trials. The FDA also may require a post-approval clinical study as a condition of approval. To perform clinical trials for significant risk devices in the United States on an unapproved product, we are required to obtain an IDE from the FDA. The FDA may also require a filing for approval prior to marketing products that are modifications of existing products or new indications for existing products. Moreover, after clearance/approval is given, if the product is shown to be hazardous or defective, the FDA and foreign regulatory agencies have the power to withdraw the clearance or approval, as the case may be, or require us to change the device, its manufacturing process or its labeling, to supply additional proof of its safety and effectiveness or to recall, repair, replace or refund the cost of the medical device. Because we currently export medical devices manufactured in the United States that have not been approved by the FDA for distribution in the United States, we are required to obtain approval/registration in the country to which we are exporting and maintain certain records relating to exports and make these available to the FDA for inspection, if required.

Human Cells, Tissues and Cellular and Tissue-Based Products

Prior to the spin-off of SeaSpine, Integra manufactured medical devices derived from human tissue (demineralized bone tissue).

The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing, or consisting of, human cells or tissue intended for transplantation into a human patient. Examples include bone, ligament, skin and cornea.

Some HCT/Ps fall within the definition of a biological product, medical device or drug regulated under the FD&C Act. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to HCT/Ps and, in addition, with requirements applicable to biologics, devices or drugs, including premarket clearance or approval from the FDA.

Section 361 of the Public Health Service Act (“PHSA”), authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as “361” HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting.

The American Association of Tissue Banks (“AATB”) has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become an AATB-accredited tissue establishment. In addition, some

states have their own tissue banking regulations. We are licensed or have permits for tissue banking in California, Florida, New York and Maryland.

National Organ Transplant Act. Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA

payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby reducing our future revenue and profitability.

Postmarket Requirements. After a device is cleared or approved for commercial distribution, numerous regulatory requirements apply. These include the FDA Quality System Regulations which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical devices; the FDA's general prohibition against promoting products for unapproved or 'off-label' uses; the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and the Reports of Corrections and Removals regulation, which require manufacturers to report recalls and field corrective actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act.

Medical Device Regulations

We also are required to register with the FDA as a medical device manufacturer. As such, our manufacturing sites are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements and other legal requirements for labeling and promotion. If the FDA believes that a company is not in compliance with applicable regulations, it may issue a warning letter, institute proceedings to detain or seize products, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and may recommend criminal prosecution to the U.S. Department of Justice.

Medical device regulations also are in effect in many of the countries in which we do business outside the United States. These laws range from comprehensive medical device approval and Quality System requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. Under the European Union Medical Device Directive, medical devices must meet the Medical Device Directive standards and receive CE Mark Certification prior to marketing in the European Union (the “EU”). CE Mark Certification requires a comprehensive quality system program, technical documentation and data on the product, which are then reviewed by a Notified Body. A Notified Body is an organization designated by the national governments of the European Union member states to make independent judgments about whether a product complies with the requirements established by each CE marking directive. The Medical Device Directive, ISO 9000 series and ISO 13485 are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. Other countries are also instituting regulations regarding medical devices or interpreting and enforcing existing regulations more strictly. Compliance with these regulations requires extensive documentation and clinical reports for all of our products, revisions to labeling, and other requirements such as facility inspections to comply with the registration requirements. A recognized Notified Body audits our facilities annually to verify our compliance with the ISO 13485 Quality System standard.

Certain countries, as well as the EU, have issued regulations that govern products that contain materials derived from animal sources. Regulatory authorities are particularly concerned with materials infected with the agent that causes bovine spongiform encephalopathy (“BSE”), otherwise known as mad cow disease. These regulations affect our dermal regeneration products, duraplasty products, hernia repair products, biomaterial products for the spine, nerve and tendon repair products and certain other products, all of which contain material derived from bovine tissue. Although we take great care to provide that our products are safe and free of agents that can cause disease, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for prion transmission. Significant new regulations, a ban of our products, or a movement away from bovine-derived products because of an outbreak of BSE could have a material adverse effect on our current business or our ability to expand our business. See “Item 1A. Risk Factors - Certain of our products contain materials derived from animal sources and may become subject to additional regulation.”

Other regulations

Anti-Bribery Laws. In the United States, we are subject to laws and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws that regulate the means by which companies in the health care industry may market their products to hospitals and health care professionals and may compete by discounting the prices of their products. Similar anti-bribery laws exist in many of the countries in which we sell our products outside of the United States, as well as the United States Foreign Corrupt Practices Act (which addresses the activities of U.S. companies in foreign markets). Our products also are subject to regulation regarding reimbursement, and U.S. healthcare laws apply when a customer submits a claim for a product that is reimbursed under a federally funded healthcare program. These global laws require that we exercise care in designing our sales and marketing practices, including involving interactions with healthcare professionals, and customer discount

arrangements. See “Item 1A. Risk Factors - Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.”

Import-export. Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, and import-export. Among other things, these laws restrict, and in some cases can prevent, United States companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in our business dealings with entities in and from foreign countries.
Hazardous materials. Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. We are subject to country-specific, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We believe that our environmental, health and safety procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations. However, risk of accidental releases or injury from these materials is possible. These risks are managed to minimize or eliminate associated business impacts. In the event of this type of accident, we could be held liable for damages that may result, and any liability could exceed our resources. We could be subject to a regulatory shutdown of a facility that could prevent the distribution and sale of products manufactured there for a significant period of time, and we could suffer a casualty loss that could require a shutdown of the facility in order to repair it, any of which could have a material, adverse effect on our business. Although we continuously strive to maintain full compliance with respect to all applicable global environmental, health and safety laws and regulations, we could incur substantial costs to fully comply with future laws and regulations, and our operations, business or assets may be negatively affected. Furthermore, global environmental, health and safety compliance is an ongoing process. Integra has compliance procedures in place for Employee Health & Safety programs, driven by a centrally led organizational structure that ensures proper implementation, which is essential to our overall business objectives.
In addition to the above regulations, we are and may be subject to regulation under country-specific federal and state laws, including, but not limited to, requirements regarding record keeping, and the maintenance of personal information, including personal health information. As a public company, we are subject to the securities laws and regulations, including the Sarbanes-Oxley Act of 2002. We also are subject to other present, and could be subject to possible future, local, state, federal and foreign regulations.
Third-Party Reimbursement. Healthcare providers that purchase medical devices generally rely on third-party payors, including, in the United States, the Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. Reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payors, or denial of, or provision of uneconomical reimbursement for new products may affect our customers' revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers' healthcare services has the potential to significantly affect our operations and revenue.
INTELLECTUAL PROPERTY
We seek patent and trademark protection for our key technology, products and product improvements, both in the United States and in selected foreign countries. When determined appropriate, we have enforced and plan to continue to enforce and defend our patent and trademark rights. In general, however, we do not rely solely on our patent and trademark estate to provide us with any significant competitive advantages as it relates to our existing product lines. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. In an effort to protect our trade secrets, we have a policy of requiring our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements also provide that all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential,

except in specified circumstances.

AccuDrain®, Advansys®, Ascension®, BioFix®, BioMotion®, Bold®, Budde®, Buzz™, Camino Capture™, CRW® CUSA®, DigiFuse®, DuraGen®, DuraSeal®, First Choice®, Futura™, Hallu®, HeliCote®, HeliPlug®, HeliTape®, HeliMend®, Helistat®, Helitene®, Integra®, IPP-ON®, Jarit®, Licox®, LimiTorr™, Luxtec®, MemoFix®, MicroFrance®, Miltex®, Movement®, NeuraGen®, NeuraWrap™, NuGrip®, Omni-Tract®, OSV II®, Qwix®, Padgett®, Panta®, PriMatrix®, PyroSphere®, Redmond™, Ruggles®, SafeGuard®, Salto Talaris®, Subtalar MBA®, SurgiMend®, TenoGlide®, Ti6®, Tibiaxys®, TissueMend®, Titan™ , Trel-X™, Trel-XC®, Trel-XPress™, TruArch®, Uni-CP®, Uni-Clip®, and the Integra logo are some of the material trademarks of Integra LifeSciences Corporation and its subsidiaries. MAYFIELD® is a registered trademark of SM USA, Inc., and is used by Integra under license.

EMPLOYEES

At December 31, 2015, we had approximately 3,500 employees engaged in production and production support for warehouse, engineering and facilities, quality assurance, quality control, research and development, regulatory and clinical affairs, sales, marketing, administration and finance. Except for certain employees at our facilities in France and Mexico, none of our employees is subject to a collective bargaining agreement.

FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Financial information about our geographical areas is set forth under “Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Geographic Product Revenues and Operations” and in our financial statements Note 15, Segment and Geographic Information, to our consolidated financial statements.

SOURCES OF RAW MATERIALS

In general, raw materials essential to our businesses are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Certain of our products, including our dermal regeneration products, duraplasty products, wound care products, bone void fillers, nerve and tendon repair products and certain other products, contain material derived from bovine tissue. We take great care to provide that our products are safe and free of agents that can cause disease. In particular, the collagen used in the products that Integra manufactures is derived either from the deep flexor tendon of cattle less than 24 months old from New Zealand, a country that has never had a reported case of bovine spongiform encephalopathy, or from the United States or from fetal dermis. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon is in the lowest-risk category for BSE transmission, and is therefore considered to have a negligible risk of containing the agent that causes BSE.

SEASONALITY

Revenues during our fourth quarter tend to be stronger than other quarters because many hospitals increase their purchases of our products during the fourth quarter to coincide with the end of their budget cycles in the U.S. In general, our first quarter usually has lower revenues than the preceding fourth quarter, the second and third quarters have higher revenues than the first quarter, and the fourth quarter revenues are the highest in the year. The main exceptions to this pattern occur because of material intervening acquisitions.

AVAILABLE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”). In accordance with the Exchange Act, we file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may view our financial information, including the information contained in this report, and other reports we file with the Securities and Exchange Commission, on the Internet, without charge as soon as reasonably practicable after we file them with the Securities and Exchange Commission, in the “SEC Filings” page of the Investor Relations section of our website at www.integralife.com. You may also obtain a copy of any of these reports, without charge, from our investor relations department, 311 Enterprise Drive, Plainsboro, NJ 08536. Alternatively, you may view or obtain reports filed with the Securities and Exchange Commission at the SEC Public Reference Room at 100 F Street, N.E. in Washington, D.C. 20549, or at the Securities and Exchange Commission's Internet site at www.sec.gov. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements in this report, including statements under “Business” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act. These forward-looking statements are subject to a number of risks, uncertainties and assumptions about us including, among other things:

- general economic and business conditions, both nationally and in our international markets;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- anticipated trends in our business;
- anticipated demand for our products, particularly capital equipment;
- our ability to produce collagen-based products in sufficient quantities to meet sales demands;
- our expectations concerning our ongoing restructuring, integration and manufacturing transfer and expansion activities;
- existing and future regulations affecting our business, and enforcement of those regulations;
- our ability to obtain additional debt and equity financing to fund capital expenditures and working capital requirements and acquisitions;
- physicians' willingness to adopt our recently launched and planned products, third-party payors' willingness to provide or continue reimbursement for any of our products and our ability to secure regulatory approval for products in development;
- initiatives launched by our competitors;
- our ability to protect our intellectual property, including trade secrets;
- our ability to complete acquisitions, integrate operations post-acquisition and maintain relationships with customers of acquired entities;