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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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Amendment No. 1  
To  
FORM S-1  
REGISTRATION STATEMENT  
Under  
The Securities Act of 1933

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**OrthoPediatrics Corp.**

(Exact name of Registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**3841**

(Primary Standard Industrial  
Classification Code Number)

**26-1761833**

(I.R.S. Employer  
Identification Number)

**2850 Frontier Drive  
Warsaw, IN 46582  
(574) 268-6379**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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**Mark C. Throdahl  
President and Chief Executive Officer  
OrthoPediatrics Corp.  
2850 Frontier Drive  
Warsaw, IN 46582  
(574) 268-6379**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

**If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.** ☐

**If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.** ☐

**If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.** ☐

**If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.** ☐

**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.**

Large accelerated filer ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.00025 par value per share	\$	\$

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes offering price of shares that the underwriters have the option to purchase.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated April 22, 2016

# Shares ORTHOPEDIATRICS CORP. Common Stock



\$ per share

- OrthoPediatrics Corp. is offering shares.
- We anticipate that the initial public offering price will be between \$ and \$ per share.
- This is our initial public offering and no public market currently exists for our shares.
- Proposed NASDAQ trading symbol: "KIDS."

This investment involves risks. See "Risk Factors" beginning on page 11.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discount <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to OrthoPediatrics Corp.	\$	\$

(1) See "Underwriting" for additional information regarding underwriting compensation.

The underwriters have an option to purchase up to additional shares of common stock from us at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved the securities described herein or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to investors on or about , 2016.

Piper Jaffray

Stifel

William Blair

The date of this prospectus is , 2016.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Until , 2016 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We use various of our trademarks, including, without limitation, ORTHOPEDIATRICS, PEDIFLEX, PEDIFRAG, PEDILOC, PEDINAIL, PEDIPLATES and RESPONSE, in this prospectus. This prospectus also includes trademarks, trade names and service marks that are the property of other organizations.

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Solely for convenience, trademarks and trade names referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we or the applicable owner will not assert, to the fullest extent under applicable law, our or its rights to these trademarks and trade names.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the section entitled “Risk Factors” and our financial statements and the related notes thereto included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, references in this prospectus to “OrthoPediatrics,” “the Company,” “our company,” “we,” “us” and “our” refer to OrthoPediatrics Corp. together with its sole subsidiary.*

### OrthoPediatrics

We are the only medical device company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. We design, develop and commercialize innovative orthopedic implants and instruments to meet the specialized needs of pediatric surgeons and their patients, who we believe have been largely neglected by the orthopedic industry. We currently serve three of the largest categories in this market. We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

Children are not just small adults. Their skeletal anatomy and physiology differs significantly from that of adults, which affects the way in which children with orthopedic conditions are managed surgically. Historically, there have been a limited number of implants and instruments specifically designed for the unique needs of children. As a result, pediatric orthopedic surgeons often improvise with adult implants repurposed for use in children, resort to freehand techniques with adult instruments and use implants that can be difficult to remove after being temporarily implanted. These improvisations may lead to undue surgical trauma and morbidity.

We address this unmet market need and sell the broadest product offering specifically designed for children with orthopedic conditions. We currently market 17 surgical systems that serve three of the largest categories within the pediatric orthopedic market: (1) trauma and deformity, (2) complex spine and (3) anterior cruciate ligament, or ACL, reconstruction procedures. We expect to expand our product offering to address additional categories of the pediatric orthopedic market, such as foot and ankle, hand and wrist, clavicle, pelvis and other sports-related injuries.

Our products have proprietary features designed to:

- protect a child’s growth plates;
- fit a wide range of pediatric anatomy;
- enable earlier surgical intervention;
- enable precise and reproducible surgical techniques; and
- ease implant removal.

Our products are used by pediatric orthopedic surgeons, who, unlike orthopedic surgeons focused on treating adults, are, for the most part, generalists treating a wide range of congenital, developmental and traumatic orthopedic conditions. As a result, these surgeons generally represent a single call point for our broad range of products. We believe our products complement one another because they are often used by the same surgeons, and the successful use of one system may create demand for the others. In 2015, there were approximately 1,300 members of the Pediatric Orthopedic Society of North America, or POSNA, and we estimate that 62% of U.S. pediatric trauma and deformity and complex spine surgeries were performed in only 268 hospitals. Based on our experience, we believe that pediatric orthopedic procedures outside of the United States are also highly concentrated. ACL reconstruction procedures are less concentrated, and the vast majority are performed in ambulatory surgery centers.

We have the only global sales organization focused exclusively on pediatric orthopedics. Our organization has a deep understanding of the unique nature of children’s clinical conditions and surgical procedures as well as an appreciation of the tremendous sense of responsibility pediatric orthopedic surgeons feel for the children whom parents have entrusted to their care. We provide these surgeons with

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dedicated support, both in and out of the operating room. As of December 31, 2015, our U.S. sales organization consisted of 34 independent sales agencies employing more than 90 sales representatives specifically focused on pediatrics. Increasingly, these sales agencies are making us the anchor line in their businesses or representing us exclusively. Outside of the United States, our sales organization consisted of 21 independent distributors in 29 countries.

We collaborate with pediatric orthopedic surgeons in developing new surgical systems that improve the quality of care. We have an efficient product development process that relies upon teams of engineers, commercial personnel and surgeon advisors. Since inception, our average clearance time with the U.S. Food and Drug Administration, or the FDA, has been 74 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is due in part to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children. We believe our products are characterized by stable pricing, few reimbursement issues and attractive gross margins.

We believe clinical education is critical to advancing the field of pediatric orthopedics. Cumulatively, we are the largest financial contributor to the five primary orthopedic surgical societies that conduct pediatric clinical education and research. We are the major sponsor of continuing medical education, or CME, courses in pediatric spine and pediatric orthopedics, which are focused on fellows and young surgeons. In 2015, we conducted more than 240 training workshops, which was more than double the number of workshops we held in 2014. We believe these workshops help surgeons recognize our commitment to their field. We believe our commitment to clinical education has helped to increase our account presence while promoting familiarity with our products and loyalty among fellows and young surgeons.

We have established a corporate culture built on the cause of improving the lives of children with orthopedic conditions. We believe our higher corporate purpose captures the hearts and minds of our employees and makes them committed to doing everything better, faster and at lower cost. This culture allows us to attract and retain talented, high-performing individuals.

For the years ended December 31, 2011 and 2015, our revenue was \$10.2 million and \$31.0 million, respectively, reflecting a compound annual growth rate, or CAGR, of 32%. For the years ended December 31, 2014 and 2015, our revenue was \$23.7 million and \$31.0 million, respectively, and our net loss was \$9.5 million and \$7.9 million, respectively. As of December 31, 2015, our accumulated deficit was \$71.6 million.

We believe we have a history of efficient capital utilization, and we intend to scale our business model by continuing to implement the successful strategy that has sustained our growth. Due to the high concentration of pediatric orthopedic surgeons in comparatively few hospitals, we believe we can accelerate the penetration of our addressable market in a capital-efficient manner and further strengthen our position as the category leader in pediatric orthopedics. The primary challenge to maintaining our growth in a market that has not historically relied on age-specific implants and instruments has been overcoming older surgeons' familiarity with repurposing adult implants for use in children. We believe our efforts in surgeon training, collaboration and marketing address this inertia, particularly with younger surgeons.

### **Unmet Market Needs**

Due to the size of the pediatric orthopedic market compared to the adult market, we believe that no other diversified orthopedic company has committed the resources necessary to develop a sales and product development infrastructure focused on this market, resulting in the following unmet needs:

#### *Lack of Commercial Infrastructure Dedicated to Pediatric Orthopedic Surgeons*

The lack of commercial infrastructure in pediatric orthopedics has the following implications:

- little dedicated sales presence for pediatric orthopedic surgeons and limited support during surgery;

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- few opportunities for pediatric orthopedic surgeons to participate in new product development; and
- few opportunities for pediatric orthopedic surgeons early in their careers to obtain specialized training on new technologies and techniques.

### *Relative Absence of Orthopedic Implants and Instruments Specifically Designed for Children*

We believe the relative absence of implants and instruments specifically designed for the unique skeletal anatomy and physiology of children has led surgeons to improvise with adult implants repurposed for use in children. The use of adult implants in children may:

- violate the growth plates, leading to growth arrest and subsequent deformities;
- not fit the greater curvature of pediatric bones, resulting in compromised clinical outcomes;
- have insufficient strength when used inappropriately in children, leading to implant failure or breakage;
- result in improper anatomical alignment of soft tissues, lengthen recovery times and lead to premature joint replacement;
- require freehand surgical techniques, leading to less accurate implant placement;
- be difficult to remove due to bony on-growth associated with the titanium typically used in adult implants, resulting in unnecessary surgical trauma;
- require lengthier and more invasive surgical approaches; and
- reduce the confidence of pediatric orthopedic surgeons in the accuracy and procedural consistency they require to achieve high standards of care.

### **Our Exclusive Focus on Pediatric Orthopedic Surgery**

We believe we are the only company that has committed the resources necessary to create a global sales and product development infrastructure focused on the pediatric orthopedic implant market. Our goal is to build an enduring company committed to addressing this market's unmet needs by providing the following:

#### *Only Commercial Infrastructure Dedicated to Pediatric Orthopedic Surgeons*

- dedicated sales support to pediatric orthopedic surgeons;
- participation of pediatric orthopedic surgeons in new product development; and
- leading supporter of pediatric orthopedic surgical societies and clinical education.

#### *Comprehensive Portfolio of Products Specifically Designed for Children*

We have developed the only comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions within the three categories of the pediatric orthopedic market that we currently serve. Our products include proprietary features designed to:

- protect a child's growth plates;
- fit a wide range of pediatric anatomy;
- enable earlier surgical intervention;
- enable precise and reproducible surgical techniques;
- ease implant removal;
- allow for less invasive surgical techniques; and
- enhance surgeon confidence.



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### **Our Competitive Strengths**

We believe our focus and experience in pediatric orthopedic surgery, combined with the following principal competitive strengths, will allow us to continue to grow our sales and expand our market opportunity.

- *Exclusive Focus on Pediatric Orthopedics.* We were founded with the mission of improving the lives of children with orthopedic conditions, a patient population which we believe has been largely neglected by the orthopedic industry. We believe our exclusive focus on pediatric orthopedics has generated strong brand equity in the pediatric orthopedic surgeon community.
- *Partnership with Pediatric Orthopedic Surgeons and Pediatric Surgical Societies.* We have devoted significant time and resources to developing deep relationships with pediatric orthopedic surgeons and supporting clinical education to advance the practice of pediatric orthopedic medicine. Our dedication to the pediatric orthopedic community is evidenced by our leading support of the five primary pediatric orthopedic surgical societies and sponsorship of training workshops and CME courses in pediatric spine and pediatric orthopedics. We believe collaborating with pediatric orthopedic surgeons has helped to promote familiarity with our products and loyalty among fellows and surgeons early in their careers.
- *Comprehensive Portfolio of Innovative Orthopedic Products Designed Specifically for Children.* We have developed the only comprehensive portfolio of implants and instruments specifically designed for children with orthopedic conditions. Our broad product offering has made us the only provider of comprehensive solutions to pediatric orthopedic surgeons within the three categories of the pediatric orthopedic market that we currently serve.
- *Scalable Business Model.* Our ability to identify and respond quickly to the needs of pediatric orthopedic surgeons and their patients is central to our culture and critical to our continued success. We estimate that 62% of U.S. pediatric trauma and deformity and complex spine procedures in 2015 were performed in only 268 hospitals. We believe that this high concentration of procedures and our focused sales organization will enable us to address the pediatric orthopedic surgery market in a capital-efficient manner. As we continue to broaden our product offering, we believe the scalability of our business model will allow us to simultaneously increase our reach, deepen our relationships with pediatric orthopedic surgeons and help us to achieve significant returns on our investments in implant and instrument sets, product development and commercial infrastructure.
- *Unique Culture: A Different Kind of Orthopedic Company.* We have established a results-oriented, people-focused corporate culture dedicated to improving the lives of children with orthopedic conditions. We believe this culture allows us to attract and retain talented, high performing professionals. We believe our focus and commitment to pediatric orthopedics has also enhanced our reputation among pediatric orthopedic surgeons as the only diversified orthopedic company focused on their field.

We believe these sources of competitive advantage provide us with the means to expand and defend our position as category leader and constitute barriers to entry that would require significant time, focus and investment for a competitor to overcome.

### **Our Strategy**

Our goal is to continue to enhance our leadership in the pediatric orthopedic surgery market and thereby improve the lives of children with orthopedic conditions. To achieve this goal, we have implemented a strategy that has five elements:

- increase investment in consigned implant and instrument sets to accelerate revenue growth;
- capitalize on our efficient product development process to expand our innovative products;

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- strengthen our global sales and distribution infrastructure;
- deepen our partnerships with pediatric orthopedic surgeons through clinical education and research; and
- continue to develop an engaging culture of continuous improvement.

### **Our Products**

We have developed the only comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions within the three categories of the pediatric orthopedic market that we currently serve. We believe our innovative products promote improved surgical accuracy, increase consistency of patient outcomes and enhance surgeon confidence in achieving high standards of care.

Selected examples of our product innovations include:

- *Locking Proximal Femur and Locking Cannulated Blade Systems*: the first cannulated implants and instruments specifically designed for the pediatric market that offer significant improvements over implants designed for adults, including improved fixation, more reproducible results and more stable constructs.
- *RESPONSE Spinal Deformity System*: a low-profile pedicle screw system designed for pediatric spinal deformity corrections that can withstand the significant lateral forces present in a child's spine, has the flexibility to accept both 5.5mm and 6.0mm titanium or cobalt chromium stabilizing rods and has one-handed rod reduction and de-rotation instruments.
- *PediNail Intramedullary Nail System*: the smallest size nail on the market to meet the unique needs of pediatric patients.
- *PediLoc Plating Systems*: anatomically designed to conform to the curvature of pediatric bones and allow screws to remain parallel to the growth plate.
- *ACL Reconstruction System*: what we believe to be the only commercially available product that enables surgical intervention in children whose growth plates are open while also restoring the ligament to its anatomically correct position.

We also have a large number of new product ideas under development and we aspire to launch one new surgical system and multiple line extension and product improvements every year.

### **Risks Related to Our Business**

Our business is subject to numerous risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects, that you should consider before making an investment decision. Some of the more significant risks and uncertainties relating to an investment in our company are listed below. These risks are more fully described in the "Risk Factors" section of this prospectus immediately following this prospectus summary.

- We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.
- We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.
- Our long-term growth depends on our ability to commercialize our products in development and to develop and commercialize additional products through our research and development efforts, and if we fail to do so we may be unable to compete effectively.
- We may be unable to generate sufficient revenue from the commercialization of our products to achieve and sustain profitability.

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- We lack published long-term data supporting superior clinical outcomes by our products, which could limit sales.
- If coverage and reimbursement from third-party payors for procedures using our products significantly decline, orthopedic surgeons, hospitals and other healthcare providers may be reluctant to use our products and our sales may decline.
- We may be unable to successfully demonstrate to orthopedic surgeons the merits of our products compared to those of our competitors.
- In preparing our financial statements for the fiscal year ended December 31, 2015, we identified a material weakness in our internal control over financial reporting, and our failure to remedy this or other material weaknesses could result in material misstatements in our financial statements.
- Our products and our operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- We rely on a network of third-party independent sales agencies and distributors to market and distribute our products, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.
- If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

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In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

**Corporate History and Information**

We were formed as a Delaware corporation in November 2007. Our sole subsidiary, OrthoPediatrics US Distribution Corp., was formed as a Delaware corporation in November 2012. Our principal executive offices are located at 2850 Frontier Drive, Warsaw, IN 46582, and our telephone number is (574) 268-6379. Our website address is [www.orthopediatrics.com](http://www.orthopediatrics.com). The information contained in, or accessible through, our website does not constitute part of this prospectus.

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### **THE OFFERING**

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise in full their option to acquire additional shares from us).
Option to purchase additional shares of common stock	The underwriters have a 30-day option to purchase up to a total of additional shares of common stock from us.
Use of proceeds	We intend to use the net proceeds received by us from this offering (i) to invest in implant and instrument sets for consignment to our customers, (ii) to fund research and development activities, (iii) to expand our sales and marketing programs and (iv) for working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in complementary products, technologies or businesses, but we currently have no agreements or commitments to do so. See “Use of Proceeds.”
Risk factors	You should read the “Risk Factors” section of this prospectus and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.

Proposed NASDAQ Global Market trading symbol

KIDS

The number of shares of our common stock to be outstanding after this offering set forth above is based on shares outstanding as of December 31, 2015, and does not reflect:

- 371,449 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of \$15.96 per share;
- 65,823 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$18.11 per share; and
- shares of our common stock reserved for future issuance under our 2016 Incentive Award Plan that will go into effect immediately prior to the completion of this offering, or the 2016 Plan, which includes 327,501 shares reserved for future issuance under the Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, that will be added to the shares reserved under the 2016 Plan upon its effectiveness.

Except as otherwise indicated, all information in this prospectus assumes:

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- the conversion of all shares of our Series A convertible preferred stock, \$0.00025 par value, or our Series A Preferred Stock, and of all shares of our Series B convertible preferred stock, \$0.00025 par value, or our Series B Preferred Stock, into shares of our common stock, which will occur immediately prior to the completion of this offering;
- a stock split of our common stock to be effected prior to the completion of this offering;
- no exercise of the outstanding options and warrants described above; and
- no exercise by the underwriters of their option to purchase additional shares of common stock.

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**SUMMARY CONSOLIDATED FINANCIAL DATA**

The following summary consolidated financial data has been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected for any future period. You should read this data together with our consolidated financial statements and the related notes thereto appearing elsewhere in this prospectus and the sections of this prospectus entitled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(in thousands, except share and per share information)	Year Ended December 31,	
	2014	2015
<b>Statement of operations data:</b>		
Net revenue	\$ 23,684	\$ 31,004
Cost of revenue	7,085	9,367
Gross profit	16,599	21,637
Operating expenses:		
Sales and marketing	12,185	15,033
General and administrative	9,875	11,407
Research and development	1,683	1,789
Total operating expenses	23,743	28,229
Operating loss	(7,144)	(6,592)
Other expenses:		
Interest expense	2,549	1,230
Other expense	67	31
Total other expenses	2,616	1,261
Net loss from continuing operations	(9,760)	(7,853)
(Gain) loss from discontinued operations	(211)	38
Net loss	\$ (9,549)	\$ (7,891)
Net loss attributable to common stockholders	\$ (12,804)	\$ (12,688)
Weighted average shares – basic and diluted	2,603,425	2,603,517
Net loss per share attributable to common stockholders <sup>(1)</sup> :		
Basic and diluted	\$ (4.92)	\$ (4.87)
Pro forma net loss per share (unaudited) <sup>(1)</sup> :		
Basic and diluted	\$	\$

(1) See note 11 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share. The effect of discontinued operations on loss per share has been excluded as it is not material.

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The following table presents summary balance sheet data as of December 31, 2015:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of all shares of our Series A Preferred Stock and our Series B Preferred Stock into        shares of our common stock, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of        shares of common stock by us in this offering at an assumed initial public offering price of \$        per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(in thousands)	Year Ended December 31, 2015		
	Actual	Pro Forma	Pro Forma As Adjusted
<b>Balance sheet data:</b>			
Cash	\$ 3,878	\$	\$
Working capital	16,131		
Total assets	30,691		
Long-term debt, net of current portion	13,039		
Total liabilities	19,376		
Redeemable convertible preferred stock	65,427		
Total stockholders' (deficit) equity	(54,112)		

The pro forma as adjusted balance sheet data is illustrative only and will depend on the actual initial public offering price, the number of shares we sell in this offering and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$        per share would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by \$        million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us at the assumed initial public offering price would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$        million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this prospectus before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment.*

### **Risks Related to Our Financial Condition and Capital Requirements**

***We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.***

We incurred net losses in all fiscal years since inception. We incurred net losses of \$9.5 million and \$7.9 million for the years ended December 31, 2014 and 2015, respectively. As a result of ongoing losses, as of December 31, 2015, we had an accumulated deficit of \$71.6 million. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing and other expenses. In addition, our general and administrative expenses will increase following this offering due to the additional costs associated with being a public company. The net losses we incur may fluctuate significantly from quarter to quarter. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

***We may be unable to generate sufficient revenue from the commercialization of our products to achieve and sustain profitability.***

At present, we rely solely on the commercialization of our products to generate revenue, and we expect to generate substantially all of our revenue in the foreseeable future from sales of these products. In order to successfully commercialize our products, we will need to continue to expand our marketing efforts to develop new relationships and expand existing relationships with customers, to obtain regulatory clearances or approvals for our products in additional countries, to achieve and maintain compliance with all applicable regulatory requirements and to develop and commercialize our products with new features or for additional indications. If we fail to successfully commercialize our products, we may never receive a return on the substantial investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance we have made, as well as further investments we intend to make, which may cause us to fail to generate revenue and gain economies of scale from such investments.

In addition, potential customers may decide not to purchase our products, or our customers may decide to cancel orders due to changes in treatment offerings, research and development plans, adverse clinical outcomes, difficulties in obtaining coverage or reimbursement for procedures using our products, difficulties obtaining approval from a hospital, complications with manufacturing or the utilization of technology developed by other parties, all of which are circumstances outside of our control.

In addition, demand for our products may not increase as quickly as we predict, and we may be unable to increase our revenue levels as we expect. Even if we succeed in increasing adoption of these systems by physicians, hospitals and other healthcare providers, maintaining and creating relationships with our existing and new customers and developing and commercializing new features or indications for these systems, we may be unable to generate sufficient revenue to achieve or sustain profitability.

***We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.***

Based on our current business plan, we believe our current cash, borrowing capacity under our credit and security agreements, cash receipts from sales of our products and net proceeds of this offering will be sufficient to meet our anticipated cash requirements for at least the next two years. If our available cash balances, borrowing capacity, net proceeds from this offering and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products



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as a result of the risks described in this prospectus, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to increase market adoption of our products and address competitive developments;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products;
- fund development and marketing efforts of any future products or additional features to then-current products;
- acquire, license or invest in new technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve gross margins;
- our rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- the cost of research and development activities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

Additional capital may not be available at such times or in amounts as needed by us. Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, or we may be required to significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

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### ***Our sales volumes and our results of operations may fluctuate over the course of the year.***

We have experienced and continue to experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, which may include, among other things:

- the number of products sold in the quarter;
- the unpredictability of sales of full sets of implants and instruments to our international distributors;
- the demand for, and pricing of, our products and the products of our competitors;
- the timing of or failure to obtain regulatory clearances or approvals for our products;
- the costs, benefits and timing of new product introductions;
- increased competition;
- the availability and cost of components and materials;
- the number of selling days in the quarter;
- fluctuation and foreign currency exchange rates; or
- impairment and other special charges.

### ***Our loan and security agreement with Squadron Capital, LLC contains covenants that may restrict our business and financing activities.***

In May 2014, we entered into a second amended and restated loan and security agreement, or the Loan Agreement, with Squadron Capital, LLC, or Squadron. The Loan Agreement was further amended on November 19, 2015 to add a \$7.0 million revolving credit facility. Pursuant to the Loan Agreement, Squadron has provided us with (i) a term loan credit facility in a principal amount of \$11.4 million and (ii) a revolving credit facility in a maximum principal amount at any time outstanding of up to \$7.0 million. As of December 31, 2015, we had \$11.4 million in outstanding debt under the term loan credit facility and no outstanding debt under the revolving credit facility. The Loan Agreement restricts our ability to, among other things:

- dispose of or sell our assets;
- modify our organizational documents;
- merge with or acquire other entities or assets;
- incur additional indebtedness;
- create liens on our assets;
- pay dividends; and
- make investments.

The covenants in the Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan Agreement to become immediately due and payable and terminate all commitments to extend further credit. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Indebtedness — Loan Agreement.”

If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may be unable to

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obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

### **Risks Related to Our Business and Strategy**

***Our long-term growth depends on our ability to commercialize our products in development and to develop and commercialize additional products through our research and development efforts, and if we fail to do so we may be unable to compete effectively.***

In order to increase our market share in the pediatric orthopedic markets, we must successfully commercialize our current products in development, enhance our existing product offerings and introduce new products in response to changing customer demands and competitive pressures and technologies. Our industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements and evolving industry standards. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our technology, including in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our products. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully commercialize our current products with domestic or international regulatory clearances or approvals or develop or obtain regulatory clearances or approvals to market new products. Additionally, these products and any future products might not be accepted by the orthopedic surgeons or the third-party payors who reimburse for the procedures performed with our products or may not be successfully commercialized due to other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Nevertheless, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have no experience in managing product transitions.

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***If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted.***

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. Furthermore, a malfunction by one of our products may not be detected for an extended period of time, which may result in delay or failure to remedy the condition for which the product was prescribed. Although we have established internal procedures to minimize risks that may arise from quality issues, we may be unable to eliminate or mitigate occurrences of these issues and associated liabilities.

***We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow.***

Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive and more effective than competing products and treatments. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products.

We have competitors in each of our three product categories, including the DePuy Synthes Companies (a subsidiary of Johnson and Johnson), Medtronic plc and Smith & Nephew plc. At any time, these and other potential market entrants may develop new devices or treatment alternatives that may render our products obsolete or uncompetitive. In addition, they may gain a market advantage by developing and patenting competitive products or processes earlier than we can or by obtaining regulatory clearances or market registrations more rapidly than we can. Many of our current and potential competitors have substantially greater sales and financial resources than we do. In addition, these companies may have more established distribution networks, entrenched relationships with orthopedic surgeons and greater experience in launching, marketing, distributing and selling products.

In addition, new market participants continue to enter the orthopedic industry. Many of these new competitors specialize in a specific product or focus on a particular market sector, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our products or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the orthopedic surgery market generally.

We also face a particular challenge of overcoming the long-standing practices by some orthopedic surgeons of using the products of our larger, more established competitors. Orthopedic surgeons who have completed many successful, complex surgeries using the products made by these competitors may be disinclined to adopt new products with which they are less familiar. Further, orthopedic surgeons may choose to use the products of our larger, more established competitors because of their broad and comprehensive adult orthopedic offerings. If these orthopedic surgeons do not adopt our products, then our revenue growth may slow or decline and our stock price may decline.

Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent sales agencies and distributors, both those presently working with us and those with whom we hope to work as we expand.

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***We provide implant and instrument sets for nearly all surgeries performed using our products, and maintaining sufficient levels of inventory could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.***

We are required to maintain significant levels of implant and instrument sets for consignment to our customers. The amount of this investment is driven by the number of orthopedic surgeons or hospitals using our products, and as the number of different orthopedic surgeons and hospitals that use our products increases, the number of implant and instrument sets required to meet this demand will increase. Because we do not have the sales volume of some larger companies, we may be unable to utilize our instrument sets as often and our return on assets may be lower when compared to such companies. In addition, because fewer than all of the components of each set are used in a typical surgery, certain portions of the set may become obsolete before they can be used. In the event that a substantial portion of our inventory becomes obsolete, the resulting costs associated with the inventory impairment charges and costs required to replace such inventory could have a material adverse effect on our earnings and cash flows. In addition, as we introduce new products, new implant and instrument sets may be required, with a significant initial investment required to accommodate the launch of the product.

***The provision of loaned instrument sets to our customers may implicate certain federal and state fraud and abuse laws.***

In the United States, we typically loan instrument sets for each surgery performed using our products at no additional charge to the customer. The provision of these instruments at no charge to our customers may implicate certain federal and state fraud and abuse laws. Because the provision of loaned instrument sets may result in a benefit to our customers, the government could view this practice as a prohibited transfer of value intended to induce customers to purchase our products that are used in procedures reimbursed by a federal healthcare program. For further discussion of these laws, see “— Risks Related to Regulatory Matters — We are subject to federal, state and foreign fraud and abuse laws and health information privacy and security laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.”

***We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders’ ownership, increase our debt or cause us to incur significant expense.***

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management’s attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;

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- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

***We may be unable to gain the support of leading hospitals and key opinion leaders, which may make it difficult to establish our products as a standard of care and achieve market acceptance.***

Our strategy includes educating leading hospitals and key opinion leaders in the industry. If these hospitals and key opinion leaders determine that alternative technologies are more effective or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited.

***We may be unable to successfully demonstrate to orthopedic surgeons the merits of our products compared to those of our competitors.***

Orthopedic surgeons play a significant role in determining the course of treatment and, ultimately, the type of products that will be used to treat a patient. As a result, our success depends, in large part, on our ability to effectively market to them and demonstrate to orthopedic surgeons the merits of our products compared to those of our competitors for use in treating patients. Acceptance of our products depends on educating orthopedic surgeons as to the distinctive characteristics, perceived clinical benefits, safety and cost-effectiveness of our products as compared to our competitors' products, and on training orthopedic surgeons in the proper use of our products. If we are not successful in convincing orthopedic surgeons of the merits of our products or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales, sustain our growth or achieve and sustain profitability.

Furthermore, we believe many orthopedic surgeons may be hesitant to adopt our products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that our products provide benefits or are attractive alternatives to our competitors' products. Orthopedic surgeons may be hesitant to change their surgical treatment practices for the following reasons, among others:

- lack of experience with our products;
- existing relationships with competitors and sales distributors that sell competitive products;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;

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- less attractive availability of coverage and reimbursement within healthcare payment systems compared to procedures using other products and techniques;
- costs associated with the purchase of new products and equipment; and
- the time commitment that may be required for training.

In addition, we believe recommendations and support of our products by influential orthopedic surgeons are essential for market acceptance and adoption. If we do not receive support from such orthopedic surgeons or long-term data does not show the benefits of using our products, orthopedic surgeons may not use our products. In such circumstances, we may not achieve expected sales, growth or profitability.

***If orthopedic surgeons fail to safely and appropriately use our products, or if we are unable to train orthopedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected growth.***

An important part of our sales process includes the ability to screen for and identify orthopedic surgeons who have the requisite training and experience to safely and appropriately use our products. If orthopedic surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. If we are unable to successfully identify orthopedic surgeon customers who will be able to successfully deploy our products, we may be unable to achieve our expected growth.

There is a learning process involved for orthopedic surgeons to become proficient in the use of our products. It is critical to the success of our commercialization efforts with respect to future products to train a sufficient number of orthopedic surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to increase sales. Convincing orthopedic surgeons to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts.

Although we believe our interactions with orthopedic surgeons are conducted in compliance with FDA, federal and state fraud and abuse and other applicable laws and regulations developed both nationally and in foreign countries, if the FDA or other competent authority determines that any of our activities constitute promotion of an unapproved use or promotion of an intended purpose not covered by FDA approved labeling or the current European Union product certification, or CE Mark, affixed to our product, they could request that we modify our activities, issue corrective advertising or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

***We have a limited operating history and may face difficulties encountered by early stage companies in new and evolving markets.***

We began operations in 2007. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early stage companies in new and evolving markets. These risks include our ability to:

- manage rapidly changing and expanding operations;
- establish and increase awareness of our brand and strengthen customer loyalty;
- increase the number of our independent sales agencies and international distributors to expand sales of our products in the United States and in targeted international markets;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;

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- continue to develop and enhance our products and products in development;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;
- expand our presence in existing and commence operations in new international markets; and
- attract, retain and motivate qualified personnel.

### ***Our business is subject to seasonal fluctuations.***

Our business is subject to seasonal fluctuations in that our revenue is typically higher in the summer months and holiday periods, driven by higher sales of our complex spine and trauma and deformity products, which is influenced by the higher incidence of pediatric surgeries during these periods due to recovery time provided by breaks in the school year. Additionally, our complex spine patients tend to have additional health challenges that make scheduling their procedures variable in nature. As a result of these factors, our financial results for any single quarter or for periods of less than a year are not necessarily indicative of the results that may be achieved for a full fiscal year.

### ***If we are unable to convince hospital facilities to approve the use of our products, our sales may decrease.***

In the United States, in order for orthopedic surgeons to use our devices, the hospital facilities where these orthopedic surgeons treat patients will typically require us to obtain approval from the facility's value analysis committee, or VAC. VACs typically review the comparative effectiveness and cost of medical devices used in the facility. The makeup and evaluation processes for VACs vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant VAC. For example, even if we have an agreement with a hospital system for the purchase of our products, in most cases, we must obtain VAC approval by each hospital within the system to sell at that particular hospital. Additionally, hospitals typically require separate VAC approval for each specialty in which our products are used, which may result in multiple VAC approval processes within the same hospital even if such product has already been approved for use by a different specialty group. We may need VAC approval for each different device to be used by the orthopedic surgeons in that specialty. In addition, hospital facilities and group purchasing organizations, or GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchase agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly, and time-consuming effort. If we do not obtain access to hospital facilities in a timely manner, or at all, via these VAC and purchase contract processes, or otherwise, or if we are unable to secure contracts in a timely manner, or at all, our operating costs will increase, our sales may decrease, and our operating results may be harmed. Furthermore, we may expend significant effort in these costly and time-consuming processes and still may not obtain VAC approval or a purchase contract from such hospitals or GPOs.

### ***We have limited experience in marketing and selling our products, and if we are unable to successfully expand our sales infrastructure and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.***

We have limited experience in marketing and selling our products. We began selling our products in the United States in 2008 and internationally in 2011. As of December 31, 2015, our sales organization consisted of 21 independent stocking distributors in 29 countries. Our operating results are directly dependent upon the sales and marketing efforts of our independent sales agencies and distributors. If our independent sales agencies or distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. We believe it is necessary to utilize a sales force that includes sales agencies with specific technical backgrounds that can support our customers' needs. We will also



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need to attract independent sales personnel and attract and develop marketing personnel with industry expertise. Competition for such independent sales agencies, distributors and marketing employees is intense and we may be unable to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to sustain profitability.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled independent sales agencies and distributors with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our products.

### ***We lack published long-term data supporting superior clinical outcomes enabled by our products, which could limit sales.***

We lack published long-term data supporting superior clinical outcomes enabled by our products. For this reason, orthopedic surgeons and other clinicians may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by orthopedic surgeons, would significantly reduce our ability to achieve expected sales and could prevent us from achieving and maintaining profitability.

In addition, because certain of our products have only been on the market for a few years, we have limited data with respect to treatment using these products. If future patient studies or clinical testing do not support our belief that our products offer a more advantageous treatment for a broad spectrum of pediatric orthopedic conditions, market acceptance of our products could fail to increase or could decrease.

### ***If coverage and reimbursement from third-party payors for procedures using our products significantly decline, orthopedic surgeons, hospitals and other healthcare providers may be reluctant to use our products and our sales may decline.***

In the United States, healthcare providers who purchase our products generally rely on third-party payors, including Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for products used in surgical procedures, the additional cost associated with the use of our products can impact the profit margin of the hospital or surgery center where the surgery is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for the procedures using our products may make it difficult for existing customers to continue using, or adopt, our products and could create additional pricing pressure for us. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Orthopedic surgeons, hospitals and other healthcare providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. If third-party payors issue non-coverage policies or if our customers are not reimbursed at adequate levels, this could adversely effect sales of our products.

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In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program's updates to hospital and physician payments. With respect to physician payments, in the past, when the application of the prescribed statutory formula resulted in lower payment, Congress passed interim legislation to prevent the reductions. However, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit-based incentive bonus program for Medicare physicians beginning in 2019. At this time, it is unclear how the introduction of the merit-based incentive bonus program will impact overall physician reimbursement under the Medicare program. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor.

Moreover, some healthcare providers in the United States have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer surgical procedures or by requiring the use of the least expensive clinically appropriate products available. Additionally, as a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for our products and cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for orthopedic implants and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline.

The marketability of our products may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***Our employees, consultants, independent sales agencies and distributors and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, consultants, independent sales agencies and distributors and other commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by

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our employees, sales agencies, distributors and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

***Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

***We bear the risk of warranty claims on our products.***

While we have no history of warranty claims, have no warranty reserves and had no warranty expense for the years ended December 31, 2014 or 2015, we bear the risk of warranty claims on the products we supply. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

***The proliferation of physician-owned distributorships could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.***

Physician-owned distributorships, or PODs, are product distributors that are owned, directly or indirectly, by physicians. PODs derive a portion, or substantially all, of their revenue from selling, or arranging for the sale of, products ordered by the physician-owners for use in procedures the physician-owners perform on their own patients at hospitals and other facilities that purchase from or through the POD, or otherwise generate revenue based directly or indirectly on product orders arranged for by physician-owners.

On March 26, 2013, the Office of Inspector General of the U.S. Department of Health and Human Services, or the DHHS, issued a special fraud alert on PODs and stated that it views PODs as inherently suspect under the federal Anti-Kickback Statute and is concerned about the proliferation of PODs. Notwithstanding the DHHS's concern about PODs, the number of PODs in the spinal surgery industry may continue to grow as economic pressures increase throughout the industry, hospitals, insurers and physicians search for ways to reduce costs and, in the case of the physicians, search for ways to increase their incomes. PODs and the physicians who own, or partially own, them have significant market knowledge and access to the orthopedic surgeons who use our products and the hospitals that purchase our products and thus the growth of PODs may reduce our ability to compete effectively for business from orthopedic surgeons who own such distributorships.

## **Risks Related to Administrative, Organizational and Commercial Operations and Growth**

### ***We may be unable to manage our anticipated growth effectively, which could make it difficult to execute our business strategy.***

We have been growing rapidly and have a relatively short history of operating as a commercial company. For example, our revenue grew from \$23.7 million for the year ended December 31, 2014 to \$31.0 million for the year ended December 31, 2015. We intend to continue to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality of or delivery timelines of our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. These increases in scale or expansion of personnel may not be successfully implemented.

### ***The loss of our senior management or our inability to attract and retain highly skilled salespeople and engineers could negatively impact our business.***

Our success depends on the skills, experience and performance of the members of our executive management team. The individual and collective efforts of these employees will be important as we continue to develop our products and as we expand our commercial activities. We believe there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and the loss or incapacity of existing members of our executive management team could negatively impact our operations if we experience difficulties in hiring qualified successors. We do not maintain key man life insurance with any of our employees. We have employment agreements with each of the members of our senior management; however, the existence of these employment agreement does not guarantee our retention of these employees for any period of time.

Our commercial, supply chain and research and development programs and operations depend on our ability to attract and retain highly skilled salespeople and engineers. We may be unable to attract or retain qualified managers, salespeople or engineers in the future due to the competition for qualified personnel among medical device businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, supply chain and research and development programs. All of our employees are at-will, which means that either we or the employee may terminate his or her employment at any time. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

### ***We face risks associated with our international business.***

We market and sell our products in 29 countries outside of the United States. During the years ended December 31, 2014 and 2015, approximately 22% and 20% of our revenue was attributable to our international customers, respectively. These customers are generally allowed to return products, and some are thinly capitalized. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. We expect our

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international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- having to comply with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;
- fluctuations in foreign currency exchange rates;
- imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- differing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- imposition of differing labor laws and standards;
- economic, political or social instability in foreign countries and regions;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

We expect we will continue expanding into other international markets; however, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory and funding hurdles to overcome and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business.

***We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.***

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior that is required by U.S. laws or by corporate policies. We are subject to the risk that we, our U.S. employees or our employees located in other jurisdictions or any third parties such as our sales agencies and distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA and the Bribery Act of 2010, or the U.K. Anti-Bribery Act. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of “off books” slush funds from which such improper payments can be made.

As a substantial portion of our revenue is, and we expect will continue to be, from jurisdictions outside of the United States, we face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or

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other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors clearly state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, our distributors may not comply with U.S. laws, including the FCPA. In addition, we operate in certain countries in which the government may take an ownership stake in an enterprise and such government ownership may not be readily apparent, thereby increasing potential anti-corruption law violations. Any violation of the FCPA and U.K. Anti-Bribery Act or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations. In addition, we have internal ethics policies with which we require our employees to comply in order to ensure that our business is conducted in a manner that our management deems appropriate. If these anti-corruption laws or internal policies were to be violated, our reputation and operations could also be substantially harmed. Further, detecting, investigating and resolving actual or alleged violations is expensive and can consume significant time and attention of our senior management. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage.

### ***Our results may be impacted by changes in foreign currency exchange rates.***

We have international operations and, as a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets or our costs could increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

### ***We will incur significant costs as a result of operating as a public company and our management expects to devote substantial time to public company compliance programs.***

As a public company, we will incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, and The NASDAQ Global Market, or NASDAQ. We estimate that our incremental cost from operating as a public company may be between \$1.5 million and \$2.0 million per year. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel will devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Wall Street Reform and Consumer Protection Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

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***As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.***

To comply with the requirements of being a public company, we will likely need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on NASDAQ.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the JOBS Act, depending on whether we choose to rely on certain exemptions set forth in the JOBS Act.

***In preparing our financial statements for the fiscal year ended December 31, 2015, we identified a material weakness in our internal control over financial reporting, and our failure to remedy this or other material weaknesses could result in material misstatements in our financial statements.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Our management identified a material weakness in our internal control over financial reporting as of December 31, 2015. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified as of December 31, 2015 resulted from the fact that we did not have sufficient financial reporting and accounting controls over complex accounting transactions to address complex U.S. generally accepted accounting principles, or GAAP, considerations and applicable SEC rules and regulations.

We have begun to implement remedial measures designed to address this material weakness, including: (i) the hiring of additional personnel with the appropriate financial reporting experience to expand our financial management and reporting infrastructure and further develop and document our accounting policies and financial reporting procedures with respect to complex accounting transactions; (ii) the retention of an additional accounting firm, as needed, to provide technical consulting services with respect to complex accounting transactions; and (iii) the establishment and implementation of policies and procedures to ensure adherence to accounting policies, rules and regulations and to provide enhanced financial analysis and quality control with respect to complex accounting transactions. If our remedial measures are insufficient to address this material weakness, or if additional material weaknesses



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or significant deficiencies in our internal control are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results.

***If we experience significant disruptions in our information technology systems, our business may be adversely affected.***

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into our systems and obtain proprietary information.

***We may be subject to various litigation claims and legal proceedings.***

We, as well as certain of our officers and distributors, may be subject to other claims or lawsuits. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines.

***If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for orthopedic surgery procedures. These surgeries involve significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. Furthermore, if orthopedic surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

We have had, and continue to have, a small number of product liability claims relating to our products, and in the future, we may be subject to additional product liability claims.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;



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- loss of revenue;
- the inability to commercialize new products or product candidates; and
- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

In addition, we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product or product candidate that is the subject of any such claim.

### ***Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.***

A major earthquake, fire or other disaster (such as a major flood, tsunami, volcanic eruption or terrorist attack) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' damaged manufacturing facilities; these delays could be lengthy and costly. If any of our customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations, those of our suppliers and customers and the ability to travel.

### **Risks Related to Regulatory Matters**

#### ***Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.***

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals;

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withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

***We may not receive the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.***

An element of our strategy is to continue to upgrade our products, add new features and expand clearance or approval of our current products to new indications. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a premarket approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market each of our products requiring such clearance. Any modifications to these existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA’s satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, in response to industry and healthcare provider

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concerns regarding the predictability, consistency and rigor of the 510(k) clearance process, the FDA initiated an evaluation, and in January 2011, announced several proposed actions intended to reform the 510(k) clearance process. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several “Medical Device Regulatory Improvements” and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances.

In order to sell our products in member countries of the EEA our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our surgical systems, which would prevent us from selling them within the EEA.

We or our distributors will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell our products.

***Modifications to our products may require new 510(k) clearances or PMA approvals, and may require us to cease marketing or recall the modified products until clearances are obtained.***

Any modification to a 510(k)-cleared product that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer’s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject

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to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Furthermore, the FDA's ongoing review of the 510(k) clearance process may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) notification for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. For example, the FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) for modifications or changes to a previously cleared device. The FDA is expected to issue revised guidance, originally issued in 1997, to assist device manufacturers in making this determination. It is unclear whether the FDA's approach in this new guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. The FDA continues to review its 510(k) clearance process, which could result in additional changes to regulatory requirements or guidance documents, which could increase the costs of compliance or restrict our ability to maintain current clearances.

***Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.***

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

***If treatment guidelines for the orthopedic conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.***

If treatment guidelines for the orthopedic conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign the applicable product and seek new clearances or approvals from the FDA. Our 510(k) clearances from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could suffer.

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***The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.***

Our products have been cleared by the FDA for specific indications. We train our marketing personnel and independent sales agencies and distributors to not promote our products for uses outside of the FDA-cleared indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

***Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.***

We are subject to the FDA’s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA’s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. We have in the past conducted several voluntary recalls of devices with lot-specific quality issues. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product’s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our

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ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

***If we or our distributors do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of the United States.***

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

***Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the EU Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation, the Medical Devices Regulation. Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

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In October 2013, the European Parliament approved a package of reforms to the European Commission's proposals. Under the revised proposals, only designated "special notified bodies" would be entitled to conduct conformity assessments of high-risk devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group, or MDCG (a new, yet to be created body chaired by the European Commission and representatives of certain European states), for an opinion. These new procedures may result in a longer or more burdensome assessment of our new products.

If adopted, the Medical Devices Regulation is expected to enter into force sometime in 2016 and become applicable three years thereafter. In its current form it would, among other things, also impose additional reporting requirements on manufacturers of high-risk medical devices, impose an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance and provide for more strict clinical evidence requirements.

***We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.***

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in substantial civil or criminal penalties, including criminal fines of up to \$25,000, imprisonment of up to five years, civil penalties under the Civil Monetary Penalties Law of up to \$50,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of up to \$11,000 for each false claim submitted, plus three times the amounts paid for such claims, and exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose penalties of not less than \$5,500 and not more than \$11,000 per claim, plus three times the amount of damages which the government sustains because of the submission of a false claim, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;



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- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit annual reports to CMS and failure to do so may result in civil monetary penalties up to an aggregate of \$150,000 per year (plus up to an aggregate of \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to \$50,000 per violation, not to exceed \$1.5 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to \$250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages up to \$25,000 per violation on behalf of residents of his or her state; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.



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These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. We have a variety of arrangements with our customers that could implicate these laws, including, among others, our consignment arrangements and our practice of loaning instrument sets to customers at no additional cost. We have also entered into consulting agreements and royalty agreements with physicians, including some who have ownership interests in us and/or influence the ordering of or use our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. We could be adversely affected if regulatory agencies determine our financial relationships with such physicians to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

### ***Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.***

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the Affordable Care Act:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Under the Consolidated Appropriations Act, 2016, the excise tax has been suspended from January 1, 2016 to December 31, 2017, and, absent further legislative action, will be reinstated starting January 1, 2018;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expands the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future.

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In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

***Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.***

Our third-party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials, but we do reserve funds to address these claims at both the federal and state levels. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines, which could be substantial.

### **Risks Related to Our Reliance on Third Parties**

***We rely on a network of third-party independent sales agencies and distributors to market and distribute our products, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.***

We rely on our network of independent sales agencies and distributors to market and distribute our products in both the United States and international markets.

In the United States, our products are primarily sold by a network of 34 independent sales agencies. We may not be successful in maintaining strong relationships with our independent sales agencies. In addition, our independent sales agencies are not required to sell our products on an exclusive basis and also are not required to purchase any minimum quantity of our products. The failure of our network of independent sales agencies to generate U.S. sales of our products and promote our brand effectively would impair our business and results of operations.

We also sell our products in international markets, primarily through a network of 21 independent distributors. We sell our products in 29 countries outside of the United States, and we expect a significant amount of our revenue to come from international sales for the foreseeable future. In the past, we have experienced issues collecting payments from certain of our independent distributors and we may again experience such issues in the future.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. We cannot control the efforts and resources our

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third-party sales agencies and distributors will devote to marketing our products. Our sales agencies and distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing and selling efforts that enable the products to develop, achieve or sustain market acceptance in their respective jurisdictions. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. If we are unable to attract additional international distributors, our international revenue may not grow.

If any of our independent sales agencies or distributors were to cease to do business with us, our sales could be adversely affected. Some of our independent sales agencies and distributors have historically accounted for a material portion of our sales volume, including one independent sales agency that accounted for greater than 10% of our revenue in 2015, and if any such agency or distributor were to cease to sell and market our products, our sales could be adversely affected. In addition, if a dispute arises with a sales agency or distributor or if a sales agency or distributor is terminated by us or goes out of business, it may take time to locate an alternative sales agency or distributor, to seek appropriate regulatory approvals and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated agent or distributor could be harmed. Any of our sales agencies or distributors could become insolvent or otherwise become unable to pay amounts owed to us when due. Any of these factors could reduce our revenue from affected markets, increase our costs in those markets or damage our reputation. If an independent sales agency or distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales.

In any such situation in which we lose the services of an independent sales agency or distributor, we may need to seek alternative sales agencies or distributors, and our sales may be adversely affected. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified independent sales agencies or distributors to work with us. We may be unable to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified independent sales agencies or distributors would prevent us from expanding our business and generating sales.

As a result of our reliance on third-party sales agencies and distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party sales agencies or distributors become unsatisfactory, including the failure of such sales agencies or distributors to properly train orthopedic surgeons in the utilization of our products, we may experience delays in meeting our customers' product demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose current or potential customers.

***We rely on third-party contract manufacturers to assemble our products, and a loss or degradation in performance of these contract manufacturers could have a material adverse effect on our business and financial condition.***

We rely on a small number of third-party contract manufacturers in the United States to assemble our products. If any of these contract manufacturers fails to adequately perform, our revenue and profitability could be adversely affected. Inadequate performance could include, among other things, the production of products that do not meet our quality standards, which could cause us to seek additional sources of manufacturing. Additionally, our contract manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change contract manufacturers due to any termination of our relationships with our contract manufacturers, we may lose revenue, experience manufacturing delays, incur increased costs or otherwise suffer impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative manufacturing relationships on similar terms or without delay. Furthermore, our contract manufacturers could require us to move to another one of their production facilities. This could disrupt our ability to fulfill orders during a transition and impact our ability to utilize our current supply chain. In addition, we currently use FMI-Hansa Medical Products, LLC and Structure Medical, LLC as two of our suppliers for

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components of our products. Each of these entities is affiliated with Squadron. See “Certain Relationships and Related Person Transactions — Squadron — Supply Relationships.”

***Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.***

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

***We rely on a limited number of third-party suppliers for the majority of our products and may be unable to find replacements or immediately transition to alternative suppliers.***

We rely on several suppliers for the majority of our products, with whom we do not have long-term supply contracts. These suppliers may be unwilling or unable to supply these products to us reliably and at the prices and levels we anticipate or are required by the market. For us to be successful, our suppliers must be able to provide us with products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these products, and if we cannot obtain an acceptable substitute. If we are required to transition to new third-party suppliers for certain products, the use of products furnished by these alternative suppliers could require us to alter our operations.

Furthermore, if we are required to change the manufacturer of our products, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those products. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar international regulatory authorization may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

### **Risks Related to Intellectual Property**

***If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.***

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We own numerous issued patents and pending patent applications that relate to our platform technology. Specifically, as of December 31, 2015, we owned seven issued U.S. patents and six issued foreign patents and we had five pending U.S. patent applications and nine foreign patent applications. Assuming all required fees are paid, issued U.S. patents owned by us will expire between 2024 and 2032.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our

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products, any additional features we develop for our products or any new products. Other parties may have developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications may not issue as patents;
- we will be unable to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable;

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- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

***Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or impact our stock price.***

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. Although we are presently unaware of any such third-party claims, in the future, we may receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and

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contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.***

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an



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employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

### ***We may be unable to enforce our intellectual property rights throughout the world.***

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

### ***Third parties may assert ownership or commercial rights to inventions we develop.***

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

### ***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.



***Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.***

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

**Risks Related to This Offering and Ownership of Our Common Stock**

***The price of our common stock may be volatile, and you may be unable to resell your shares at or above the initial public offering price.***

Prior to this offering, there was no public market for shares of our common stock. The initial public offering price for the shares of our common stock sold in this offering will be determined by negotiation between the underwriters and us. This price may not reflect the market price of our common stock following this offering. You may be unable to sell your shares of common stock at or above the initial public offering price due to fluctuations in the market price of our common stock. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- commercial success and market acceptance of our products;
- success of our competitors in developing or commercializing products;
- ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;
- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;

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- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- business disruptions caused by earthquakes, fires or other natural disasters; and
- issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for companies like ours in particular, have from time to time experienced extreme volatility that have has been often unrelated to the operating performance of the issuer. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance.

***We may be subject to securities litigation, which is expensive and could divert our management's attention.***

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns.

***We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act. We may remain an emerging growth company until as late as December 31, 2021, though we may cease to be an emerging growth company earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30, in which case we would cease to be an emerging growth company as of the following December 31, or (ii) if our gross revenue exceeds \$1 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

***Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline.***

If our existing stockholders or optionholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and legal restrictions on resale discussed in this prospectus lapse, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline. Based on shares of common stock outstanding as of December 31, 2015, upon the completion of this offering, we will have outstanding a total of      shares of common stock, assuming no exercise of the underwriters' option to

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purchase additional shares of common stock. Of these shares, the      shares of common stock sold by us in this offering, plus any shares sold upon exercise of the underwriters' option to purchase additional shares of common stock, will be freely tradable without restriction, unless held by our affiliates, in the public market immediately following this offering.

After the lock-up agreements expire,      shares of common stock will be eligible for sale in the public market, subject in certain instances to volume limitations under Rule 144 under the Securities Act, with respect to shares held by directors, executive officers and other affiliates. The underwriters may, however, in their sole discretion, permit our directors, our executive officers and other stockholders and the holders of our outstanding options who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements. Sales of these shares, or perceptions that they will be sold, could cause the price of our common stock to decline.

In addition, based on the number of shares subject to outstanding awards under the 2007 Plan, or available for issuance thereunder, as of December 31, 2015, and including the initial reserves under the 2016 Plan,      shares of common stock that are either subject to outstanding options, outstanding but subject to vesting or reserved for future issuance under the 2016 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. We also plan to file a registration statement permitting shares of common stock issued in the future pursuant to the 2016 Plan to be freely resold by plan participants in the public market, subject to the lock-up agreements, applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. The 2016 Plan contains provisions for the annual increase of the number of shares reserved for issuance under such plan, as described elsewhere in this prospectus, which shares we also intend to register. If the shares we may issue from time to time under the 2016 Plan are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline.

Approximately      shares of common stock will be entitled to rights with respect to registration under the Securities Act, subject to the lock-up agreements described above. Such registration would result in these shares becoming fully tradable without restriction under the Securities Act when the applicable registration statement is declared effective. Sales of such shares could cause the price of our common stock to decline. See "Description of Capital Stock — Registration Rights" for additional information.

***If there is no viable public market for our common stock, you may be unable to sell your shares at or above the initial public offering price.***

Prior to this offering there has been no public market for shares of our common stock. Although we expect our common stock will be approved for listing on NASDAQ, an active trading market for our shares may never develop or be sustained following this offering. You may be unable to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***Investors in this offering will suffer immediate and substantial dilution of their investment.***

If you purchase common stock in this offering, you will pay more for your shares than our pro forma as adjusted net tangible book value per share. Based upon an assumed initial public offering price of \$      per share, the midpoint of the price range set forth on the cover page of this prospectus, you will incur immediate and substantial dilution of \$      per share, representing the difference between our assumed initial public offering price and our pro forma as adjusted net tangible book value per share. Based upon the assumed initial public offering price of \$      per share, purchasers of common stock in this offering will have contributed approximately      % of the aggregate purchase price paid by all purchasers of our

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stock and will own approximately % of our common stock outstanding after this offering. To the extent outstanding stock options or warrants are exercised, new investors may incur further dilution. For information on how the foregoing amounts were calculated, see the section titled “Dilution.”

***Our operating results for a particular period may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to fluctuations. Our operating results will be affected by numerous factors, including: variations in the level of expenses related to our products or future development programs; level of underlying demand for our products; addition or termination of clinical trials; our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; and regulatory developments affecting our products or our competitors.

If our operating results for a particular period fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe comparisons of our financial results from various reporting periods are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***We will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways which you do not agree or that may not yield a return.***

We discuss our plan for the use of the net proceeds of this offering in the sections titled “Use of Proceeds” and “Business.” However, within the scope of our plan, and in light of the various risks to our business that are set forth in this section, our management will have broad discretion over the use of the net proceeds from this offering. Because of the number and variability of factors that will determine our use of such proceeds, you may not agree with how we allocate or spend the proceeds from this offering. We may pursue commercialization and product development strategies, clinical trials, regulatory approvals or collaborations that do not result in an increase in the market value of our common stock and that may increase our losses. Our failure to allocate and spend the net proceeds from this offering effectively could harm our business, financial condition and results of operations. Until the net proceeds are used, they may be placed in investments that do not produce significant investment returns or that may lose value.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert control over matters subject to stockholder approval.***

Based on the beneficial ownership of our common stock as of December 31, 2015, after this offering, our officers and directors, together with holders of 5% or more of our outstanding common stock before this offering and their respective affiliates, will beneficially own approximately % of our common stock, assuming no exercise of the underwriters’ option to purchase additional shares of common stock. Accordingly, these stockholders will continue to have an influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors’ perception that conflicts of interest may exist or arise.

***Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.***

As of December 31, 2015, we had federal tax net operating loss carryforwards, or NOLs, of \$60.3 million, which begin to expire in 2028 unless previously utilized. In general, under Section 382 and

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383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (generally defined as a cumulative change in equity ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period) may be subject to limitations on its ability to utilize its NOLs and certain credit carryforwards to offset future taxable income and taxes. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has previously occurred or will occur as a result of this offering. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

***Provisions of our charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective upon the completion of this offering may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation that will become effective upon the completion of this offering provides that the Court of Chancery of the State of Delaware is the exclusive forum for

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(i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

***We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the Loan Agreement contains, and the terms of any future credit agreements may we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on the company. If no securities or industry analysts commence coverage of the company, the price for our common stock could be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of the company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

## **MARKET AND INDUSTRY DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations. Life Science Intelligence, Inc., the primary source for anterior cruciate ligament procedural data included in this prospectus, was commissioned by us to compile this information. In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

## USE OF PROCEEDS

We estimate that our net proceeds from our sale of      shares of common stock in this offering will be \$      million, or \$      million if the underwriters exercise their option to purchase additional shares in full, based on an assumed initial public offering price of \$      per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by \$      million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by \$      million, assuming the assumed initial public offering price stays the same.

We currently intend to use the net proceeds from this offering as follows:

- approximately \$      million to invest in implant and instrument sets for consignment to our customers;
- approximately \$      million to fund research and development activities;
- approximately \$      million to expand our sales and marketing programs; and
- the remainder for working capital and general corporate purposes.

We may also use a portion of the net proceeds from this offering to acquire or invest in complementary products, technologies or businesses, although we have no present agreements or commitments to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including the rate of adoption of our products, the expenses we incur in selling and marketing efforts, the scope of research and development efforts and other factors described under “Risk Factors” in this prospectus, as well as the amount of cash used in our operations. We therefore cannot estimate the amount of net proceeds to be used for all of the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we intend to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.



## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock. We do not currently intend to pay dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. In addition, the Loan Agreement contains, and the terms of any future credit agreements may we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

## CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2015:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of all shares of our Series A Preferred Stock and Series B Preferred Stock into shares of our common stock, which will occur immediately prior to the completion of this offering, and the filing of our amended and restated certificate of incorporation; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of common stock by us in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with the information contained elsewhere in this prospectus, including “Use of Proceeds,” “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes thereto.

(in thousands, except share and per share information)	As of December 31, 2015		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash	\$ 3,878	\$	\$
Total debt	\$ 13,140	\$	\$
Preferred stock, \$ par value; no shares authorized, issued or outstanding, actual; shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—		
Series A preferred stock, \$0.00025 par value; 1,000,000 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	21,654		
Series B preferred stock, \$0.00025 par value; 6,000,000 shares authorized, 4,446,978 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	43,773		
Stockholders’ (deficit) equity:			
Common stock; \$0.00025 par value; 12,000,000 shares authorized, 3,489,567 shares issued and outstanding, actual; 12,000,000 shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1		
Additional paid-in capital	17,449		
Accumulated deficit	(71,562)		
Total stockholders’ (deficit) equity	(54,112)		
Total capitalization	\$ 24,455	\$	\$

The pro forma as adjusted data is illustrative only, and our capitalization following this offering will depend on the actual initial public offering price, the number of shares we sell in this offering and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted cash, additional paid-in capital, total stockholders equity and total capitalization by \$ million, assuming the number of shares offered by

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us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) our pro forma as adjusted cash, additional paid-in capital, total stockholders equity and total capitalization by \$      million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the assumed initial public offering price stays the same.

The number of shares of our common stock outstanding shown in the foregoing table and calculations excludes:

- 371,449 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2015 at a weighted average exercise price of \$15.96 per share;
- 65,823 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$18.11 per share; and
- shares of our common stock reserved for future issuance under the 2016 Plan, which includes 327,501 shares of common stock reserved for future issuance under the 2007 Plan that will be added to the shares reserved under the 2016 Plan upon its effectiveness.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of December 31, 2015, our net tangible book value was \$10.4 million, or \$4.00 per share. We calculate net tangible book value by taking the amount of our total tangible assets, reduced by the amount of our total liabilities, and then dividing that amount by the total number of shares of common stock outstanding.

As of December 31, 2015, our pro forma net tangible book value would have been \$      million, or \$      per share, after giving effect to the conversion of all shares of our Series A Preferred Stock and our Series B Preferred Stock into      shares of our common stock, which will occur immediately prior to the completion of this offering.

As of December 31, 2015, our pro forma as adjusted net tangible book value would have been \$      million, or \$      per share, after giving effect to our sale of      shares in this offering at an assumed initial public offering price of \$      per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in net tangible book value of \$      per share to existing stockholders and an immediate dilution in net tangible book value of \$      per share to new investors purchasing shares in this offering at the initial public offering price. We determine dilution by subtracting pro forma as adjusted net tangible book value per share of common stock from the initial public price per share of common stock.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Net tangible book value per share as of December 31, 2015	\$ 4.00
Increase in net tangible book value per share attributable to conversion of preferred stock	
Pro forma net tangible book value per share as of December 31, 2015	
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this offering	
Pro forma as adjusted net tangible book value per share as of December 31, 2015	
Dilution per share to new investors in this offering	\$

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by \$     , and dilution in pro forma net tangible book value per share to new investors by \$     , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase of 1.0 million in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by \$      and decrease the dilution to investors participating in this offering by \$      per share, assuming that the assumed initial public offering price remains the same. Similarly, a decrease of 1.0 million in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by \$      and increase the dilution to investors participating in this offering by \$      per share, assuming that the assumed initial public offering price remains the same.

If the underwriters exercise their option to purchase      additional shares of our common stock in full, the pro forma as adjusted net tangible book value after the offering would be \$      per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be

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\$ per share and the dilution per share to new investors would be \$ per share, in each case assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, on the pro forma as adjusted basis described above, as of December 31, 2015, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors in this offering. As the table shows, new investors purchasing shares in this offering will pay a price per share substantially higher than the average price our existing stockholders paid. The table below gives effect to the sale of new shares of common stock in this offering at the initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

(in thousands, except share and per share information)	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
Investors participating in this offering					
Total		100.0%	\$	100.0%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise their option to purchase additional shares of our common stock in full, the percentage of shares of common stock held by existing stockholders will decrease to % of the total number of shares of our common stock outstanding after this offering, and the number of shares held by new investors will increase to , or % of the total number of shares of our common stock outstanding after this offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) total consideration paid by new investors, total consideration paid by all stockholders and the average price per share paid by all stockholders by \$ million, \$ million and \$ , respectively, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed public offering price per share.

The foregoing tables and calculations exclude:

- 371,449 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2015 at a weighted average exercise price of \$15.96 per share;
- 65,823 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$18.11 per share; and
- shares of our common stock reserved for future issuance under the 2016 Plan, which includes 327,501 shares of common stock reserved for future grant or issuance under the 2007 Plan that will be added to the shares reserved under the 2016 Plan upon its effectiveness.

To the extent any of these outstanding options is exercised or new awards are granted under our equity compensation plans, there will be further dilution to new investors. If all of such outstanding options had been exercised as of December 31, 2015, the pro forma as adjusted net tangible book value after this offering would have been \$ per share, and total dilution to new investors would have been \$ per share.

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**SELECTED CONSOLIDATED FINANCIAL DATA**

This selected consolidated financial data has been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected for any future period. You should read this data together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the section of this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(in thousands, except share and per share information)	Year Ended December 31,	
	2014	2015
<b>Statement of operations data:</b>		
Net revenue	\$ 23,684	\$ 31,004
Cost of revenue	7,085	9,367
Gross profit	16,599	21,637
Operating expenses:		
Sales and marketing	12,185	15,033
General and administrative	9,875	11,407
Research and development	1,683	1,789
Total operating expenses	23,743	28,229
Operating loss	(7,144)	(6,592)
Other expenses:		
Interest expense	2,549	1,230
Other expense	67	31
Total other expenses	2,616	1,261
Net loss from continuing operations	(9,760)	(7,853)
(Gain) loss from discontinued operations	(211)	38
Net loss	\$ (9,549)	\$ (7,891)
Net loss attributable to common stockholders	\$ (12,804)	\$ (12,688)
Weighted average shares – basic and diluted	2,603,425	2,603,517
Net loss per share attributable to common stockholders <sup>(1)</sup> :		
Basic and diluted	\$ (4.92)	\$ (4.87)
Pro forma net loss per share (unaudited) <sup>(1)</sup> :		
Basic and diluted	\$	\$

(1) See note 11 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share. The effect of discontinued operations on loss per share has been excluded as it is not material.

(in thousands)	Year Ended December 31,	
	2014	2015
<b>Balance sheet data:</b>		
Cash	\$ 6,581	\$ 3,878
Total assets	35,828	30,691
Total long-term liabilities	14,633	13,039
Total liabilities	17,851	19,376
Redeemable convertible preferred stock	60,630	65,427
Total stockholders’ deficit	(42,653)	(54,112)

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are the only medical device company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. We design, develop and commercialize innovative orthopedic implants and instruments to meet the specialized needs of pediatric surgeons and their patients, who we believe have been largely neglected by the orthopedic industry. We currently serve three of the largest categories in this market. We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

We sell implants and instruments to our customers for use by pediatric orthopedic surgeons to treat orthopedic conditions in children. We provide our implants in sets that consist of a range of implant sizes and include the instruments necessary to perform the surgical procedure. In the United States, our customers typically expect us to have full sets of implants and instruments on site at each hospital but do not purchase the implants until they are used in surgery. Accordingly, we must make an up-front investment in inventory of consigned implants and instruments before we can generate revenue from a particular hospital and we maintain substantial levels of inventory at any given time.

We currently market 17 surgical systems that serve three of the largest categories within the pediatric orthopedic market: (i) trauma and deformity, (ii) complex spine and (iii) ACL reconstruction. We rely on a broad network of third parties to manufacture the components of our products, which we then inspect and package. We believe our innovative products promote improved surgical accuracy, increase consistency of outcomes and enhance surgeon confidence in achieving high standards of care. In the future, we expect to expand our product offering within these categories, as well as to address additional categories of the pediatric orthopedic market.

The majority of our revenue has been generated in the United States, where we sell our products through a network of 34 independent sales agencies employing more than 90 sales representatives specifically focused on pediatrics. These independent sales agencies distribute our products and are compensated through a combination of sales-based commissions and performance bonuses. We do not sell our products through or participate in physician-owned distributorships, or PODs.

We market and sell our products internationally in 29 countries through independent stocking distributors. Our independent distributors manage the billing relationship with each hospital in their respective territories and are responsible for servicing the product needs of their surgeon customers. Starting in 2016, we intend to supplement our use of independent distributors with a direct international sales program in select markets. For the years ended December 31, 2014 and 2015, international sales accounted for approximately 22% and 20% of our revenue, respectively.

We believe there are significant opportunities for us to strengthen our position in U.S. and international markets by increasing investments in consigned implant and instrument sets, strengthening our global sales and distribution infrastructure and expanding our product offering.

For the years ended December 31, 2011 and 2015, our revenue was \$10.2 million and \$31.0 million, respectively, reflecting a compound annual growth rate, or CAGR, of 32%. For the years ended

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December 31, 2014 and 2015, our revenue was \$23.7 million and \$31.0 million, respectively, and our net loss was \$9.5 million and \$7.9 million, respectively. As of December 31, 2015, our accumulated deficit was \$71.6 million.

### **Components of our Results of Operations**

#### ***Revenue***

In the United States, we generate revenue primarily from the sale of our implants, and to a much lesser extent, from the sale of our instruments. We primarily consign our implants and instrument sets to independent sales agencies, who in turn deliver them to hospitals for use in procedures. We then supply these independent sales agencies with products to replace the consigned inventory as it is used in surgeries. We primarily recognize revenue when the products are used by the hospital for surgeries on a case by case basis. On rare occasions, hospitals purchase products for their own inventory, and revenue is recognized when the products are shipped and the title and risk of loss passes to the hospital customer.

Outside of the United States, we sell our products through independent stocking distributors. These distributors are generally allowed to return products, and some are thinly capitalized. Based on our history of collections and returns from international distributors, we have concluded that collectability is not reasonably assured at the time of delivery. Accordingly, we do not recognize international revenue and associated cost of revenue at the time title transfers, but rather when cash has been received from the distributor in payment. Until such payment, the cost of revenue is recorded as inventory held by international distributors, net of estimated unreturnable inventory on the balance sheet.

We expect that our U.S. and international sales will grow in the near term across all three of our product categories as we continue to introduce new product line extensions, consign more implant and instrument sets in the United States, open new international markets and expand the number of our clinical training programs. We also expect to increase our revenue by expanding our customer base both in the United States and internationally by strengthening our global sales and distribution infrastructure.

#### ***Cost of Revenue and Gross Margin***

Our cost of revenue consists primarily of products purchased from third-party suppliers, inbound freight, excess and obsolete inventory adjustments and royalties. Our implants and instruments are manufactured to our specifications by third-party suppliers. The majority of our implants and instruments are produced in the United States. We recognize cost of revenue for consigned implants at the time the implant is used in surgery and the related revenue is recognized. Prior to their use in surgery, the cost of consigned implants is recorded as inventory in our balance sheet. The costs of instruments are typically capitalized and not included in cost of revenue. We expect our cost of revenue to increase in absolute dollars due primarily to increased sales volume and changes in the geographic mix of our sales as our international operations tend to have a higher cost of revenue as a percentage of sales.

Our gross profit is calculated by subtracting our cost of revenue from revenue and is expected to increase in absolute dollars due primarily to increased sales volume and sales mix to customers based in the United States. Our gross profit as a percentage of total revenue, or gross margin, was similar across 2014 and 2015. Our gross margin is impacted by the mix of revenue between the United States, where we earn a higher gross margin that is required to pay sales commissions, and international, where we earn a lower gross margin because the distributor is responsible for paying sales commissions.

#### ***Sales and Marketing Expenses***

Our sales and marketing expenses primarily consist of commissions to our domestic independent sales agencies, as well as compensation, commissions, benefits and other related personnel costs. Commissions and bonuses are generally based on a percentage of sales. Our international independent distributors purchase implant and instrument sets and replenishment stock for resale, and we do not pay commissions or any other sales-related costs for international sales. We expect our sales and marketing expenses to continue to increase in absolute dollars with the commercialization of our current and pipeline products and continued investment in our global sales organization to reach new customers.



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### **General and Administrative Expenses**

Our general and administrative expenses primarily consist of compensation, benefits and other related costs for personnel employed in our executive management, administration, finance, legal, quality and regulatory, product management, warehousing, information technology and human resources departments, including stock-based compensation for all personnel, as well as facility costs. We include insurance expenses in general and administrative expenses, as well as costs related to the maintenance and protection of our intellectual property portfolio. Our general and administrative expenses also include the depreciation of our capitalized instrument sets, which represented \$1.3 million and \$1.6 million for the years ended December 31, 2014 and 2015, respectively. We expect our general and administrative expenses to continue to increase in absolute dollars as we hire additional personnel to support the growth of our business. In addition, we expect to incur increased expenses as a result of being a public company. We expect the growth rate of our general and administrative expenses will be lower than the growth rate of our revenue.

### **Research and Development Expenses**

Our research and development expenses primarily consist of costs associated with engineering, product development, consulting services, outside prototyping services, outside research activities, materials and development of our intellectual property portfolio. We also include related personnel and consultants' compensation expense. We expect research and development expenses to continue to increase both in absolute dollars and as a percentage of revenue as we continue to develop new products to expand our product offering, broaden our intellectual property portfolio and add research and development personnel.

### **Other Expenses**

Our other expenses primarily consist of borrowing costs and expenses related to long-term debt.

### **Discontinued Operations**

In 2014, we made a strategic business decision to no longer sell biologics products. The revenue, cost of revenue and expenses from this product line were netted together and the gain or loss was reported as (gain) loss from discontinued operations on our statement of operations. As of December 31, 2015, the entire biologics product line was liquidated. Below is a summary of the discontinued operations financial results:

(in thousands)	Year Ended December 31,	
	2014	2015
Revenue	\$ 845	\$ —
Expenses	634	—
Results from operating activities	211	—
Loss on sale of assets held for sale	—	38
(Gain) loss from discontinued operations	<u>\$ (211)</u>	<u>\$ 38</u>

### **Results of Operations**

The following table sets forth our results of operations for the years ended December 31, 2014 and 2015:

(in thousands, except percentages)	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2014	2015		
Revenue	\$ 23,684	\$ 31,004	\$ 7,320	31%
Cost of revenue	7,085	9,367	2,282	32
Sales and marketing expenses	12,185	15,033	2,848	23
General and administrative expenses	9,875	11,407	1,532	16
Research and development expenses	1,683	1,789	106	6
Other expenses	2,616	1,261	(1,355)	(52)
Net loss from continuing operations	<u>\$ (9,760)</u>	<u>\$ (7,853)</u>	<u>\$ (1,907)</u>	<u>(20)</u>

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### *Revenue*

The following tables set forth our revenue by geography and product category for the years ended December 31, 2014 and 2015:

(in thousands, except percentages)	Revenue by Geography Year Ended December 31,			
	2014		2015	
	Amount	% of revenue	Amount	% of revenue
U.S.	\$ 18,421	78%	\$ 24,910	80%
International	5,263	22	6,094	20
Total	<u>\$ 23,684</u>	<u>100%</u>	<u>\$ 31,004</u>	<u>100%</u>

(in thousands, except percentages)	Revenue by Product Category Year Ended December 31,			
	2014		2015	
	Amount	% of revenue	Amount	% of revenue
Trauma and deformity	\$ 19,325	82%	\$ 22,475	73%
Complex spine	3,556	15	7,446	24
ACL reconstruction/other	803	3	1,083	3
Total	<u>\$ 23,684</u>	<u>100%</u>	<u>\$ 31,004</u>	<u>100%</u>

Revenue increased \$7.3 million, or 31%, from \$23.7 million for the year ended December 31, 2014 to \$31.0 million for the year ended December 31, 2015. The increase was due primarily to complex spine sales growth of \$3.9 million, or 109%, which was primarily driven by the launch of our 5.5mm/6.0mm RESPONSE spine system in May 2015, trauma and deformity sales growth of \$3.1 million, or 16%, which was driven by continued clinical education and sales effectiveness, and ACL reconstruction/other sales growth of \$0.3 million, or 35%. Nearly all of the increase was due to an increase in the unit volume sold and not a result of price changes.

### *Cost of Revenue and Gross Margin*

Cost of revenue increased \$2.3 million, or 32%, from \$7.1 million for the year ended December 31, 2014 to \$9.4 million for the year ended December 31, 2015. The increase was due primarily to increased unit volume. Gross margin was 70% for both of the years ended December 31, 2014 and 2015.

### *Sales and Marketing Expenses*

Sales and marketing expenses increased \$2.8 million, or 23%, from \$12.2 million for the year ended December 31, 2014 to \$15.0 million for the year ended December 31, 2015. The increase was due primarily to increased sales commission and shipping expenses, both driven by higher unit volume.

### *General and Administrative Expenses*

General and administrative expenses increased \$1.5 million, or 16%, from \$9.9 million for the year ended December 31, 2014 to \$11.4 million for the year ended December 31, 2015. The increase was due primarily to an increase in cash bonus compensation, non-cash stock based compensation and other expenses to support the growth of our business. Depreciation expenses increased \$0.3 million, or 19%, from \$1.6 million for the year ended December 31, 2014 to \$1.9 million for the year ended December 31, 2015. The increase in depreciation expenses was primarily a result of prior increased investments in consigned surgical instrument sets.

### *Research and Development Expenses*

Research and development expenses increased \$0.1 million, or 6%, from \$1.7 million for the year ended December 31, 2014 to \$1.8 million for the year ended December 31, 2015. The increase was due primarily to continued investment in new product development in the trauma and deformity and complex spine product categories.

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### *Other Expenses*

Other expenses were \$2.6 million and \$1.3 million for the years ended December 31, 2014 and 2015, respectively. Other expenses for both of these periods consisted primarily of interest expenses on long-term debt. The decrease in other expenses was primarily driven by a refinancing event in May 2014, pursuant to which \$22.0 million of debt was converted to redeemable convertible preferred equity.

### **Liquidity and Capital Resources**

We have incurred operating losses since inception and negative cash flows from operating activities for the years ended December 31, 2014 and 2015 of \$9.9 million and \$0.9 million, respectively. As of December 31, 2015, we had an accumulated deficit of \$71.6 million. We anticipate that our losses will continue in the near term as we continue to expand our product portfolio and invest in additional consigned implant and instrument sets to support our expansion into existing and new markets. Since inception, we have funded our operations primarily with proceeds from the sales of our common and preferred stock, convertible securities and debt, as well as through sales of our products. As of December 31, 2015 we had cash and cash equivalents of \$3.9 million.

We believe our existing cash and cash equivalents, borrowing capacity under the Loan Agreement, cash receipts from sales of our products and net proceeds from this offering will be sufficient to meet our anticipated cash requirements for at least the next two years. Nonetheless, from time to time, we may seek additional financing sources to meet our working capital requirements, make continued research and development investments and make capital expenditures needed for us to maintain and grow our business. We may not be able to obtain additional financing on terms favorable to us, if at all. It is also possible that we may allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on products or technologies that are unsuccessful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may have to scale back our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock, including the shares of common stock sold in this offering.

### **Cash Flows**

The following table sets forth our cash flows from operating, investing and financing activities for the years ended December 31, 2014 and 2015:

(in thousands)	Year Ended December 31,	
	2014	2015
Net cash used in operating activities	\$ (9,922)	\$ (892)
Net cash used in investing activities	(3,276)	(1,713)
Net cash provided by (used in) financing activities	19,721	(98)
Net increase (decrease) in cash and cash equivalents	\$ 6,523	\$ (2,703)

### *Cash Used in Operating Activities*

Net cash used in operating activities was \$9.9 million and \$0.9 million for the years ended December 31, 2014 and 2015, respectively. The primary use of this cash was to fund our operations related to the development and commercialization of our products in each of these years. The improvement of approximately \$9.0 million in net cash used in operations for 2015 was primarily due to a \$1.7 million improvement in our net loss and a \$6.0 million cash flow from inventories and inventories held by international distributors. Net cash provided by (used for) working capital was \$(2.7) million and \$3.9 million for the years ended December 31, 2014 and 2015, respectively. During 2014, the primary driver of working capital cash use was a \$2.3 million increase in inventories held by international distributors as we shipped sets and finished goods inventory to new distributors. During 2015, the primary driver of working capital cash generation was a \$1.6 million reduction in inventories held by international

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distributors as we did not establish new distributor relationships and we returned some sets and finished goods inventory from new distributors that lacked sufficient capital. During 2015, we also reduced warehouse inventory by \$1.6 million and other working capital by \$0.7 million as we refocused on cash preservation. We had a net loss of \$9.5 million for the year ended December 31, 2014, as compared to a net loss of \$7.9 million for the year ended December 31, 2015, which drove a partial difference in the use of operating cash between the two periods.

### *Cash Used in Investing Activities*

Net cash used in investing activities was \$3.3 million and \$1.7 million for the years ended December 31, 2014 and 2015, respectively. Net cash used in investing activities consisted primarily of purchases of instrument sets, which were consigned in the United States, of \$3.1 million and \$2.2 million for the years ended December 31, 2014 and 2015, respectively. These amounts were partially offset by cash collected for assets held for sale related to our discontinued business operations.

### *Cash Provided By (Used In) Financing Activities*

Net cash provided by (used in) financing activities was \$19.7 million and \$(0.1) million for the years ended December 31, 2014 and 2015, respectively. Net cash used in financing activities during 2015 consisted primarily of mortgage payments. Net cash provided by financing activities during 2014 consisted primarily of proceeds from the issuance of preferred stock of \$16.9 million and proceeds from the issuance of debt of \$4.0 million, which was partially offset by payments on promissory notes and convertible term notes of \$1.1 million.

## **Indebtedness**

### *Loan Agreement*

In May 2014, we entered into a second amended and restated loan agreement, or the Loan Agreement, with Squadron. The Loan Agreement was further amended on November 19, 2015 to add a \$7.0 million revolving credit facility. Pursuant to the Loan Agreement, Squadron has provided us with (i) a term loan credit facility in a principal amount of \$11.4 million and (ii) a revolving credit facility in a maximum principal amount at any time outstanding of up to \$7.0 million. The largest principal amount outstanding at any time during the years ended December 31, 2014 and 2015 was \$11.4 million. As of December 31, 2015, we had \$11.4 million in outstanding debt under the term loan credit facility and no outstanding debt under the revolving credit facility. Borrowings under the Loan Agreement are secured by substantially all of our assets and are unconditionally guaranteed by our sole subsidiary.

There are no financial covenants associated with the Loan Agreement. However, there are negative covenants that prohibit us from, among other things, transferring any of our material assets, merging with or acquiring another entity, entering into a transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties and redeeming stock or paying dividends, in each case subject to certain exceptions as further detailed in the Loan Agreement.

The Loan Agreement includes events of default, the occurrence and continuation of any of which provides Squadron with the right to exercise remedies against us and the collateral securing the loans, including cash. These events of default include, among other things, the failure to pay amounts due under the credit facilities, insolvency, the occurrence of a material adverse event, which includes a material adverse change in our business, operations or properties (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than \$250,000. The occurrence of a material adverse change could result in the acceleration of payment of the debt.

We are obligated to make monthly interest-only payments on the term loan facility and any principal amount outstanding on the revolving credit facility until the earlier of: (i) a transaction pursuant to which any person acquires (a) shares of our capital stock possessing the voting power to elect a majority of our board of directors or (b) all or substantially all of our assets on a consolidated basis; or (ii) May 30, 2017, at which point the term loan facility and any principal amount outstanding on the revolving credit facility, plus all accrued, unpaid interest thereon, will become due.

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Borrowings under the term loan facility and the revolving credit facility bear interest at an annual rate of 10%. Following May 30, 2017, or the earlier occurrence and continuation of an event of default, such borrowings will bear interest at an annual rate of 18%. We may prepay the term loan facility in whole or in part without premium or penalty upon ten days' prior written notice to Squadron.

### *Mortgage Note*

In August 2013, pursuant to the purchase of our office and warehouse space, we entered into a mortgage note payable to Tawani Enterprises Inc., an entity affiliated with Squadron. Pursuant to the terms of the mortgage note, we pay Tawani Enterprises Inc. monthly principal and interest installments of \$15,543, with interest compounded at 5% until maturity in August 2028, at which time a final payment of remaining principal and interest will become due. The mortgage is secured by the related real estate and building. As of December 31, 2014 and 2015, the mortgage balance was \$1.8 million and \$1.7 million.

### **Pediatric Orthopedic Business Seasonality**

Our revenue is typically higher in the summer months and holiday periods, driven by higher sales of our trauma and deformity and complex spine products, which is influenced by the higher incidence of pediatric surgeries during these periods due to recovery time provided by breaks in the school year. Additionally, our complex spine patients tend to have additional health challenges that make scheduling their procedures variable in nature.

### **Critical Accounting Policies and Significant Judgments and Estimates**

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. We monitor and analyze these items for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting policies are most critical to understanding and evaluating our reported financial results.

### *Revenue Recognition*

In the United States, we primarily sell our implants, and to a much lesser extent our instruments, through third-party independent sales agencies to medical facilities and hospitals. Our inventory is held by field sales representatives or consigned at customer locations. For such inventory, revenue and associated cost of revenue is recognized when a product is used in a procedure. In a few cases, hospitals purchase our products for their own inventory, and such revenue and associated cost of revenue is recognized when the products are shipped or delivered and the title and risk of loss passes to the customer.

International sales are through independent stocking distributors. Generally, these distributors are allowed to return products, can be thinly capitalized and in some cases do not pay for our products until they have been resold. Based on our history of collections and returns from international distributors, we have concluded that collectability is not reasonably assured. Accordingly, we recognize international revenue and associated cost of revenue when cash is received from the distributor.

As of December 31, 2014 and 2015, we have invoiced international sales to distributors that have not been recognized as revenue totaling \$7.4 million and \$5.2 million, respectively. Associated cost of revenue, which is reported as inventory held by distributors until the related revenue is recognized, was \$4.5 million and \$2.8 million as of December 31, 2014 and 2015, respectively.

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### *Inventory Valuation*

Inventory is stated at the lower of cost or market, with cost determined using the first-in-first-out method. Inventory, which consists of implants and instruments included in deployed sets in the field or held in our warehouse, is considered finished goods and is purchased from third parties.

We evaluate the carrying value of our inventory in relations to the estimated forecast of product demand, which takes into consideration the life cycle of the products. A significant decrease in demand could result in an increase in the amount of excess inventory on hand, which could lead to additional charges for excess and obsolete inventory.

The need to maintain substantial levels of inventory impacts our estimates for excess and obsolete inventory. Each of our systems are designed to include implantable products that come in different sizes and shapes to accommodate the surgeon's needs. Typically, a small number of the set components are used in each surgical procedure. Certain components within each set may become obsolete before other components based on the usage patterns. We adjust inventory values to reflect these usage patterns and life cycle.

In addition, we continue to introduce new products, which we believe will increase our revenue. As a result, we may be required to take additional charges for excess and obsolete inventory in the future.

### *Income Taxes*

Income taxes include federal and state income taxes and deferred income taxes. We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the year in which such items are expected to be received or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates in the period that includes the enactment date. We establish a valuation allowance to offset any deferred tax assets if, based upon available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Currently, we have recorded a full valuation allowance against the deferred tax assets, as we have incurred losses to date.

### *Stock-based Compensation*

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the stock options on the date of the grant using the Black-Scholes option pricing model. The grant date fair value of such options is expensed on a straight-line basis over the period during which the employee grantee is required to provide service in exchange for the award, which is generally the vesting period. No stock options were granted during the years ended December 31, 2014 or 2015 and compensation costs related to previously granted stock options during such periods were immaterial.

We recognize compensation costs related to restricted stock granted to employees based on the estimated fair value of the awards on the date of the grant, net of estimated forfeitures, amortized over the restriction period.

Historically, for all periods prior to this offering, the fair values of the shares of common stock underlying our restricted stock and stock option awards were estimated on each grant date by management and approved by the board of directors. In order to determine the fair value of our common stock underlying such grants, we consider multiple inputs to value our common stock, including the value of equity, enterprise value and key price points in our capital structure. Given the absence of a public trading market for our common stock, we exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including the preferences and dividends of our redeemable convertible preferred stock relative to those of our common stock; our operating results and financial conditions, including our level of available capital resources; equity market conditions affecting comparable public companies; general U.S. market conditions and the lack of marketability of our common stock.

In valuing our common stock, we used the market approach, which is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. In using the

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market approach, we have considered both the guideline public company method and the precedent transaction method. We allocated the enterprise value across our classes of capital stock to determine the fair value of our common stock at each valuation date. After the equity value was allocated to the share classes, we applied a discount for lack of marketability to our common shares because we were valuing a minority interest in our company as a closely held, non-public company with no liquid market for its shares. We also considered the various rights and privileges of our redeemable convertible preferred stock relative to our common stock, including anti-dilution protection, cumulative dividend rights, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing.

For stock-based awards granted after the completion of this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

We recorded total stock-based compensation expenses of \$0.7 million and \$1.2 million for the years ended December 31, 2014 and 2015, respectively. We expect to continue to grant restricted stock and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expenses in future periods will likely increase.

The intrinsic value of all outstanding options and warrants as of December 31, 2015 was \$ , based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of December 31, 2015:

(in thousands)	Payments Due by Period <sup>(1)</sup>				
	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Long-term debt	\$ 13,140	\$ 101	\$ 11,736	\$ 124	\$ 1,179

(1) The table excludes the redemption preference of our redeemable convertible preferred stock, which is redeemable on or after May 30, 2017 at the option of the holders. The value of the accumulated redemption amount as of December 31, 2015 was \$65,427.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

### **Net Operating Losses**

As of December 31, 2015, we had federal tax net operating loss carryforwards, or NOLs, of \$60.3 million, which begin to expire in 2028 unless previously utilized. The deferred tax assets were fully offset by a valuation allowance as of December 31, 2014 and 2015, and no income tax benefit has been recognized in our consolidated statements of operations.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, annual use of our NOLs may be limited in the event that an “ownership change” occurs, which is generally defined as a cumulative change in equity ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period.

### **Recently Issued Accounting Pronouncements**

In April 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-08, “*Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360)*,” which includes amendments that change the requirements for reporting discontinued operations and require additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations that have, or will have, a major effect on the



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organization's operations and financial results should be presented as discontinued operations. Additionally, this guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The standard is applied prospectively and is effective for public entities beginning in annual periods after December 15, 2014, and interim periods within those years, with early adoption permitted. We adopted the guidance in the first quarter of 2014. This adoption did not have a material impact on our consolidated financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU 2014-15, "*Presentation of Financial Statements — Going Concern (Subtopic 205-40)*." The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We do not expect to early adopt this guidance and does not believe that the adoption of this guidance will have a material impact on our consolidated financial position, results of operations and cash flows.

In April 2015, the FASB issued ASU 2015-03, "*Interest — Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*." This update requires an entity to present debt issuance costs related to a recognized debt liability as a direct deduction from the carrying amount of that debt liability consistent with debt discounts and is effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. We do not expect this guidance to have a material impact on our consolidated financial position, results of operations or cash flows.

In July 2015, the FASB issued ASU 2015-11 "*Simplifying the Measurement of Inventory*," which is intended to narrow down the alternative methods available for valuing inventory. The new guidance does not apply to inventory currently measured using the last-in-first-out or the retail inventory valuation methods. Under the new guidance, inventory valued using other methods, including the first-in-first-out method, must be valued at the lower of cost or net realizable value. This guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We do not believe the guidance will have a material impact on our consolidated financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU 2014-09 "*Revenue from Contracts with Customers*," on the recognition of revenue for all contracts with customers designed to improve comparability and enhance financial statement disclosures. The underlying principle of this comprehensive model is that revenue is recognized to depict the transfer of promised goods or services to customers in an amount that reflects the payment to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB subsequently issued guidance which approved a one year deferral of the guidance for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017. Early adoption is permitted as of the original effective date for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. We are currently evaluating the impact of this guidance on our consolidated financial position, results of operations and cash flows.

In November 2015, the FASB issued ASU 2015-07 "*Balance Sheet Classification of Deferred Taxes*," which provides guidance on the balance sheet classification of deferred taxes. Under the current guidance, deferred tax liabilities and assets must be separated into current and noncurrent amounts in a classified statement of financial position. The new guidance requires deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The new guidance does not change the requirement that deferred tax liabilities and assets of a tax-paying component of an entity to be offset and presented as a single amount. The guidance is effective for our 2019 annual financial statements and for interim periods within 2020, with earlier application permitted as of the beginning of an interim or annual reporting period. The guidance offers two acceptable adoption methods: (i) retrospective adoption to all periods presented; or (ii) prospective adoption to all deferred tax liabilities and assets. As



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this standard only changes the classification of current deferred tax assets and liabilities to noncurrent assets and liabilities, we do not believe the adoption of this standard will not have a material effect on our consolidated financial position, results of operations or cash flows.

### **Quantitative and Qualitative Disclosures about Market Risk**

#### *Interest Rate Risk*

Our cash balances as of December 31, 2014 and 2015 consisted of cash held in an operating account that earns nominal interest income. We are exposed to market risk related to fluctuations in interest rates and bond market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of our cash holdings, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operation. Because our long-term debt under the Loan Agreement bears interest at a fixed rate, a change in market interest rate would not impact our financial condition and results of operations.

#### *Foreign Currency*

While we operate in countries other than the United States, we bill all of our sales outside of the United States in U.S. dollars. We therefore believe the risk of a significant impact on our operating income from foreign currency fluctuations is not significant. We do not currently hedge our exposure to foreign currency exchange rate fluctuations, but we may choose to do so in the future. We estimate that an immediate 10% adverse change in foreign exchange rates not currently pegged to the U.S. dollar would have decreased our reported net income by a de minimis amount for the years ended December 31, 2014 and 2015.

### **Other Company Information**

#### *JOBS Act*

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an “emerging growth company,” as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in this prospectus and in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this registration statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably

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elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### *Internal Control over Financial Reporting*

In accordance with the provisions of the Sarbanes-Oxley Act, neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period included in this prospectus. However, we and our independent registered public accounting firm have identified certain control deficiencies in the design and operation of our internal control over financial reporting that we believe constituted a material weakness in our internal control over financial reporting as of December 31, 2015. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified resulted from the fact that we did not have sufficient financial reporting and accounting controls over complex accounting transactions to address complex GAAP considerations and applicable SEC rules and regulations.

In response to this material weakness, during 2016 we have begun taking numerous steps to remediate the underlying causes of the material weakness, including: (i) the hiring of additional personnel with the appropriate financial reporting experience to expand our financial management and reporting infrastructure and further develop and document our accounting policies and financial reporting procedures with respect to complex accounting transactions; (ii) the retention of an additional accounting firm, as needed, to provide technical consulting services with respect to complex accounting transactions; and (iii) the establishment and implementation of policies and procedures to ensure adherence to accounting policies, rules and regulations and to provide enhanced financial analysis and quality control with respect to complex accounting transactions.

## BUSINESS

### OrthoPediatrics

We are the only medical device company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. We design, develop and commercialize innovative orthopedic implants and instruments to meet the specialized needs of pediatric surgeons and their patients, who we believe have been largely neglected by the orthopedic industry. We currently serve three of the largest categories in this market. We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

Children are not just small adults. Their skeletal anatomy and physiology differs significantly from that of adults, which affects the way in which children with orthopedic conditions are managed surgically. Children's bones are smaller, are more curved and have growth plates that cannot be violated without potential bone growth arrest and subsequent deformity. Furthermore, children may suffer from complex disorders such as cerebral palsy, which may pose clinical challenges and require multiple surgeries into adulthood.

Historically, there have been a limited number of implants and instruments specifically designed for the unique needs of children. As a result, pediatric orthopedic surgeons often improvise with adult implants repurposed for use in children, resort to freehand techniques with adult instruments and use implants that can be difficult to remove after being temporarily implanted. These improvisations may lead to undue surgical trauma and morbidity.

We address this unmet market need and sell the broadest product offering specifically designed for children with orthopedic conditions. We currently market 17 surgical systems that serve three of the largest categories within the pediatric orthopedic market: (1) trauma and deformity, (2) complex spine and (3) anterior cruciate ligament, or ACL, reconstruction procedures. Our products have proprietary features designed to:

- protect a child's growth plates;
- fit a wide range of pediatric anatomy;
- enable earlier surgical intervention;
- enable precise and reproducible surgical techniques; and
- ease implant removal.

We believe our innovative products promote improved surgical accuracy, increase consistency of patient outcomes and enhance surgeon confidence in achieving high standards of care. In the future, we expect to expand our product offering to address additional categories of the pediatric orthopedic market, such as foot and ankle, hand and wrist, clavicle, pelvis and other sports-related injuries.

Our products are used by pediatric orthopedic surgeons, who, unlike orthopedic surgeons focused on treating adults, are, for the most part, generalists treating a wide range of congenital, developmental and traumatic orthopedic conditions. As a result, these surgeons generally represent a single call point for our broad range of products. We believe our products complement one another because they are often used by the same surgeons, and the successful use of one system may create demand for the others. In 2015, there were approximately 1,300 members of the Pediatric Orthopedic Society of North America, or POSNA, and we estimate that 62% of U.S. pediatric trauma and deformity and complex spine surgeries were performed in only 268 hospitals. Based on our experience, we believe that pediatric orthopedic procedures outside of the United States are also highly concentrated. ACL reconstruction procedures are less concentrated, and the vast majority are performed in ambulatory surgery centers.

We have the only global sales organization focused exclusively on pediatric orthopedics. Our organization has a deep understanding of the unique nature of children's clinical conditions and surgical procedures as well as an appreciation of the tremendous sense of responsibility pediatric orthopedic surgeons feel for the children whom parents have entrusted to their care. We provide these surgeons with dedicated support, both

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in and out of the operating room. As of December 31, 2015, our U.S. sales organization consisted of 34 independent sales agencies employing more than 90 sales representatives specifically focused on pediatrics. Increasingly, these sales agencies are making us the anchor line in their businesses or representing us exclusively. Outside of the United States, our sales organization consisted of 21 independent distributors in 29 countries.

We collaborate with pediatric orthopedic surgeons in developing new surgical systems that improve the quality of care. We have an efficient product development process that relies upon teams of engineers, commercial personnel and surgeon advisors. Since inception, our average clearance time with the U.S. Food and Drug Administration, or the FDA, has been 74 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is due in part to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children. We believe our products are characterized by stable pricing, few reimbursement issues and attractive gross margins.

We believe clinical education is critical to advancing the field of pediatric orthopedics. Cumulatively, we are the largest financial contributor to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research. We are the major sponsor of continuing medical education, or CME, courses in pediatric spine and pediatric orthopedics, which are focused on fellows and young surgeons. In 2015, we conducted more than 240 training workshops, which was more than double the number of workshops we held in 2014. We believe these workshops help surgeons recognize our commitment to their field. We believe our commitment to clinical education has helped to increase our account presence while promoting familiarity with our products and loyalty among fellows and young surgeons.

We have established a corporate culture built on the cause of improving the lives of children with orthopedic conditions. We believe our higher corporate purpose captures the hearts and minds of our employees and makes them committed to doing everything better, faster and at lower cost. This culture allows us to attract and retain talented, high-performing individuals.

For the years ended December 31, 2011 and 2015, our revenue was \$10.2 million and \$31.0 million, respectively, reflecting a compound annual growth rate, or CAGR, of 32%. For the years ended December 31, 2014 and 2015, our revenue was \$23.7 million and \$31.0 million, respectively, and our net loss was \$9.5 million and \$7.9 million, respectively. As of December 31, 2015, our accumulated deficit was \$71.6 million.

We believe we have a history of efficient capital utilization, and we intend to scale our business model by continuing to implement the successful strategy that has sustained our growth. This strategy includes increasing investment in consigned implant and instrument sets in the United States and select international markets, expanding our innovative product line by leveraging our efficient product development process, strengthening our global sales and distribution infrastructure, broadening our commitment to clinical education and research and deepening our culture of continuous improvement. Due to the high concentration of pediatric orthopedic surgeons in comparatively few hospitals, we believe we can accelerate the penetration of our addressable market a capital-efficient manner and further strengthen our position as the category leader in pediatric orthopedics. The primary challenge to maintaining our growth in a market that has not historically relied on age-specific implants and instruments has been overcoming older surgeons' familiarity with repurposing adult implants for use in children. We believe our efforts in surgeon training, collaboration and marketing address this inertia, particularly with younger surgeons.

## **Industry Overview**

### *Children Have Unique Skeletal Characteristics*

Children are not just small adults. Their skeletal anatomy and physiology differs significantly from adults, which affect the way in which children with orthopedic conditions are managed surgically. These differences include:

- *Children's Bones Are Smaller.* Children's bones are significantly smaller than adult bones. Bone size and strength increases rapidly during childhood and adolescence.

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- *Children's Bones Are Growing.* Children's bones contain growth plates, or physes, that consist of developing cartilage tissue at the end of the bone, enabling skeletal growth. Bones grow lengthwise from the ends of the growth plates until skeletal maturity is reached and the growth plates close. As this occurs, some bones fuse together, reducing the 270 bones children have at birth to 206 bones by adulthood. Injury to the growth plates, including fracture or surgical trauma, can lead to growth arrest and subsequent deformity.
- *The Composition and Vasculature of Children's Bones Is Unique.* Children's bones are more porous and respond to injury and infection differently than adult bones. Children also have blood vessels that supply oxygen and nutrients to bones as they grow, which disappear when the growth plates close and the child reaches adulthood. Trauma to these blood vessels during surgery may cut off blood supply to the bone, resulting in death of the bone tissue.
- *Children's Bones Change Shape as They Grow.* Children's bones are more curved than adult bones. As children grow into adulthood, their bones change shape to accommodate the biomechanical forces exerted upon the body. For example, the curvature of the femur decreases up to 30% as a child matures.
- *Complex Disorders in Children Pose Unique Clinical Challenges.* Complex disorders such as cerebral palsy, scoliosis, brittle bone disease and hip disorders can pose significant challenges for surgical treatment. The most common such disorder is cerebral palsy, which affects approximately 500,000 children under the age of 18 in the United States and approximately 3 out of every 1,000 live births. Spastic cerebral palsy is the most common form, making up the majority of all cerebral palsy cases. Spastic cerebral palsy can produce skeletal deformities such as curvature of the spine, hip dislocation, gait abnormalities and other conditions involving joints and bones. Children suffering from these disorders often require multiple surgeries into adulthood.

We believe the challenges resulting from the unique characteristics of children's skeletal anatomy and physiology, as well as the complex disorders affecting them, are best addressed by the use of implants and instruments specifically designed for the treatment of children.

### *Pediatric Orthopedic Surgeons Are Generalists*

Unlike orthopedic surgeons focused on treating adults, pediatric orthopedic surgeons are, for the most part, generalists treating a wide range of congenital, developmental and traumatic orthopedic conditions, including limb and spine deformities, gait abnormalities, bone and joint infections, sports injuries and orthopedic trauma cases. Accordingly, they generally represent a single call point for our broad range of pediatric orthopedic implants and instruments. In 2015, there were approximately 1,300 members of POSNA, as compared to approximately 33,400 practicing orthopedic surgeons in the United States focused on the treatment of adults. The number of fellowships in pediatric orthopedics continues to grow. As generalists, these surgeons have a deep understanding of the unique nature of children's clinical conditions and surgical procedures. We believe they feel a tremendous sense of responsibility for the children whom parents have entrusted to their care.

### **Market Opportunity**

We currently serve a portion of the pediatric orthopedic implant market that we estimate represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States. The chart below provides the estimated sizes of the three categories of our U.S. addressable market opportunity, based on third-party data (including ACL Reconstruction data compiled by Life Science Intelligence, Inc. in a study that we commissioned) regarding the number of procedures performed in 2015 and our average revenue per procedure:

	<u>Trauma and Deformity</u>	<u>Complex Spine</u>	<u>ACL Reconstruction</u>
<b>U.S. Pediatric Orthopedic Implant Market</b>	\$ 401 Million	\$ 284 Million	\$ 102 Million

We estimate that the United States represented approximately 55% of the total global orthopedic implant market, both adult and pediatric, and that this geographic segmentation similarly applies to the global pediatric orthopedic implant market.

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Overviews of the three categories of the pediatric orthopedic implant market that we currently serve are as follows:

### *Trauma and Deformity*

Trauma and deformity procedures involve placing metal plates and screws on the outside of the bone or long nails inside the canal of the bone, known as intramedullary nails, to stabilize fractures and allow them to heal. Trauma and deformity procedures also include osteotomies, or surgical cutting of the bone, and the use of metal implants to correct angular bone deformities or limb length discrepancies.

### *Complex Spine*

Complex spine procedures involve the use of spinal implants, such as pedicle screws and rods, to correct curvature of the spine as a result of scoliosis, trauma or tumors.

### *ACL Reconstruction*

Anterior cruciate ligament, or ACL, reconstruction refers to the replacement of the ACL with a surgical tissue graft to restore function to the knee after injury. According to Life Science Intelligence, Inc., in a study that we commissioned, approximately 29% of ACL reconstruction procedures completed in the United States in 2015 were in patients under the age of 18. The vast majority of these procedures were performed in ambulatory surgery centers.

### *High Procedural Concentration in Trauma and Deformity and Complex Spine*

According to IMS Health, Inc., 3,425 hospitals performed pediatric trauma and deformity or complex spine procedures in the United States in 2015. Only 268 of these hospitals performed 62% of all pediatric trauma and deformity and complex spine procedures. Further, of these hospitals, 62 are children's hospitals and performed 21% of all pediatric trauma and deformity and complex spine procedures. We believe that this high concentration of pediatric trauma and deformity and complex spine procedures and our focused sales organization will enable us to address the pediatric orthopedic surgery market in a capital-efficient manner.

In the future, we expect to expand our market opportunity by addressing additional categories of the pediatric orthopedic market, such as foot and ankle, hand and wrist, clavicle, pelvis and other sports-related injuries.

### **Unmet Market Needs**

Children are not just small adults. Their skeletal anatomy and physiology require specialized implants and instruments designed to treat their orthopedic disorders appropriately. Significant investment in product development and clinical, regulatory and commercial infrastructure is required to bring a medical device to market. Due to the size of the pediatric orthopedic market compared to the adult market, we believe that no other diversified orthopedic company has committed the resources necessary to develop a sales and product development infrastructure focused on this market, resulting in the following unmet needs:

#### *Lack of Commercial Infrastructure Dedicated to Pediatric Orthopedic Surgeons*

The lack of commercial infrastructure in pediatric orthopedics has the following implications:

- little dedicated sales presence for pediatric orthopedic surgeons and limited support during surgery;
- few opportunities for pediatric orthopedic surgeons to participate in new product development; and
- few opportunities for pediatric orthopedic surgeons early in their careers to obtain specialized training on new technologies and techniques.

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### *Relative Absence of Orthopedic Implants and Instruments Specifically Designed for Children*

We believe the relative absence of implants and instruments specifically designed for the unique skeletal anatomy and physiology of children has led surgeons to improvise with adult implants repurposed for use in children. The use of adult implants in children may:

- violate the growth plates, leading to growth arrest and subsequent deformities;
- not fit the greater curvature of pediatric bones, resulting in compromised clinical outcomes;
- have insufficient strength when used inappropriately in children, leading to implant failure or breakage;
- result in improper anatomical alignment of soft tissues, lengthen recovery times and lead to premature joint replacement;
- require freehand surgical techniques, leading to less accurate implant placement;
- be difficult to remove due to bony on-growth associated with the titanium typically used in adult implants, resulting in unnecessary surgical trauma;
- require lengthier and more invasive surgical approaches; and
- reduce the confidence of pediatric orthopedic surgeons in the accuracy and procedural consistency they require to achieve high standards of care.

Historically, without pediatric-specific products, some conditions in children would go untreated. For example, tears of the ACL are common sports-related injuries. Because attempting an ACL repair on a child whose growth plates have not closed can cause growth disturbances in the leg, young athletes would often go untreated and remain sidelined until puberty.

### **Our Exclusive Focus on Pediatric Orthopedic Surgery**

We believe we are the only company that has committed the resources necessary to create a global sales and product development infrastructure focused on the pediatric orthopedic implant market. Our goal is to build an enduring company committed to addressing this market's unmet needs.

#### *Only Commercial Infrastructure Dedicated to Pediatric Orthopedic Surgeons*

- *Dedicated Sales Support to Pediatric Orthopedic Surgeons.* Our sales and marketing personnel provide dedicated sales support to pediatric orthopedic surgeons, both in and out of the operating room, to guide them through the optimal selection and use of implants and instruments to achieve desired clinical outcomes.
- *Participation of Pediatric Orthopedic Surgeons in New Product Development.* With the assistance of our Chief Medical Officer, or CMO, a highly respected former pediatric orthopedic surgeon, and the Surgeon Advisory Board he chairs, we engage with pediatric orthopedic surgeons to understand their clinical needs and develop new implants, instruments and surgical techniques that will allow them to better serve their patients. We also respond to surgeons' requests for customized implants and instruments to improve their workflows and enhance their clinical outcomes.
- *Leading Supporter of Pediatric Orthopedic Surgical Societies and Clinical Education.* Cumulatively, we donate more than any of our competitors to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research. In 2015, we conducted more than 240 training workshops focused on fellows and surgeons early in their careers, which was more than double the number of workshops we held in 2014. We believe our commitment to clinical education advances pediatric orthopedic surgery and increases our account presence, while promoting familiarity with our products and loyalty among fellows and young surgeons. We aspire to be viewed as the partner of pediatric orthopedic surgeons around the world.

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### *Comprehensive Portfolio of Products Specifically Designed for Children*

We have developed the only comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions within the three categories of the pediatric orthopedic market that we currently serve. Our products include proprietary features designed to:

- *Protect a Child's Growth Plates.* Some of our implants include patented features that enable appropriate fixation to the bone while protecting a child's growth plates.
- *Fit a Wide Range of Pediatric Anatomy.* Our implants are specifically designed to fit the unique curvature of children's bones, which changes with age.
- *Enable Earlier Surgical Intervention.* Our implants and instruments allow surgical treatment of sports-related knee injuries in young children, enable natural anatomical alignment of the ligament and avoid long-term clinical complications.
- *Enable Precise and Reproducible Surgical Techniques.* Where appropriate, our products are designed to be positioned over a guidewire. This enhances the precision of placement from traditional, freehand techniques and promotes the reproducibility of the surgical procedure.
- *Ease Implant Removal.* Where appropriate, our implants are made of stainless steel, which discourages bony on-growth and enables easier surgical removal than does the titanium typically used for adult implants.
- *Allow For Less Invasive Surgical Techniques.* Our instruments are specifically designed for use in children and are often smaller than adult instruments. This enables pediatric orthopedic surgeons in many cases to treat their patients with less invasive surgical techniques.
- *Enhance Surgeon Confidence.* Our implants and instruments promote improved surgical accuracy, increase consistency of outcomes and, we believe, enhance surgeon confidence in achieving high standards of care.

Selected examples of our product innovations include:

#### *Locking Proximal Femur and Locking Cannulated Blade Systems*

Our Locking Proximal Femur Plate and Locking Cannulated Blade systems are the first to offer cannulated implants and instruments to the pediatric market. They are designed for hip osteotomies, where a bone is cut to shorten, lengthen or change its alignment or orientation. These systems include a locking screw to secure the resulting bone fragment. These plates have a small hole, or cannula, drilled through the length of the implant. This allows the implant and its screws to fit over a guidewire and, with the use of a specialized alignment instrument, ensure optimal placement. These systems offer significant improvements over those designed for adults because they improve fixation, offer more reproducible results and create a more stable construct, thereby minimizing the risk of improper placement from traditional freehand techniques. These systems are available in multiple sizes and angles to restore the mechanical axis of the skeletal anatomy.

#### *RESPONSE Spinal Deformity System*

Our RESPONSE Spinal Deformity system is designed to treat adolescent idiopathic scoliosis. It is based on a pedicle screw specifically designed for pediatric patients, rather than one developed for adult lumbar fixation. Pedicle screws are attached directly to vertebrae and provide a means to anchor rods, which are used to realign, or reduce, and de-rotate the spine. Our system's proprietary design can withstand the significant lateral forces present when reducing and de-rotating a child's spine. This minimizes the common problem of set screws cross threading or dissociating from the head of the pedicle screw. Furthermore, our RESPONSE screws are among the lowest profile screws commercially available and are 20% shorter than those in the market-leading system, which minimizes patient discomfort. Our system has the flexibility to accept both 5.5mm and 6.0mm titanium or cobalt chromium stabilizing rods within the same pedicle screw, giving the surgeon significant flexibility during the procedure to strengthen the



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construct without replacing the screws. Our rod reduction instrument provides ergonomic one-handed clip-on and off, as well as powerful rod reduction and de-rotation in one instrument. This system is approved for use in both children and adults.

### *PediNail Intramedullary Nail System*

Our PediNail Intramedullary Nail system treats fractures and deformities of the femur and includes the smallest size nail on the market to meet the unique needs of pediatric patients. Our novel design incorporates a complex shape that enables simplified insertion, reducing the likelihood of damage to blood vessels of the femoral head and subsequent death of the bone tissue.

### *PediLoc Plating Systems*

Our PediLoc Plating systems are anatomically designed to treat fractures and correct deformities at different points of the femur and tibia. Our PediLoc systems conform to the curvature of pediatric bones and minimize the need for bending, contouring and other repurposing of adult implants during surgery, while providing superior fixation with either locking or non-locking screws. In addition, some of our patented screw seatings allow the screw to enter the bone and remain parallel to the growth plate in order to prevent damage to the growth plate. Our PediLoc systems are available in a range of sizes and contours, improve surgical precision and ease-of-use and we believe enhance surgeon confidence in treating patients with varying skeletal maturities.

### *ACL Reconstruction System*

Tears of the ACL are common sports-related injuries. Because attempting an ACL repair on a child whose growth plates have not closed can cause growth disturbances in the leg, young athletes would historically go untreated and remain sidelined until puberty. We believe our ACL system is the only commercially available product that enables surgical intervention in children whose growth plates are open while also restoring the ligament to its anatomically correct position. We developed our ACL system in collaboration with leading pediatric sports medicine surgeons to be the only comprehensive reconstruction system designed for the full spectrum of patients, from high-performance athletes to young children with open growth plates. Our ACL system is approved for ligament and tendon reconstruction in both children and adults. We believe this system expands the addressable market for sports medicine surgeries, and we are currently investigating its use in other sports medicine applications.

## **Our Competitive Strengths**

We believe our focus and experience in pediatric orthopedic surgery, combined with the following principal competitive strengths, will allow us to continue to grow our sales and expand our market opportunity.

- *Exclusive Focus on Pediatric Orthopedics.* We were founded with the mission of improving the lives of children with orthopedic conditions, a patient population which we believe has been largely neglected by the orthopedic industry. We believe we are the first diversified orthopedic company to focus exclusively on the pediatric market. Our core competencies are the development and commercialization of innovative products and technologies specifically designed to address the unmet clinical needs of pediatric orthopedic patients and satisfy the demands of the surgeons who treat them. We have developed and sell the broadest product offering specifically designed for pediatric orthopedic patients. We believe we are the only orthopedic company to have established a robust pediatric-focused infrastructure, including product development and a dedicated global commercial organization. We believe our exclusive focus on pediatric orthopedics has generated strong brand equity in the pediatric orthopedic surgeon community.
- *Partnership with Pediatric Orthopedic Surgeons and Pediatric Surgical Societies.* We have devoted significant time and resources to developing deep relationships with pediatric orthopedic surgeons and supporting clinical education to advance the practice of pediatric orthopedic medicine. We believe we are the only orthopedic company with a non-founding former pediatric orthopedic surgeon serving as CMO. This enables us to engage and

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collaborate with thought-leading surgeons and academic institutions around the world in order to develop products and technologies specifically designed to meet the needs of pediatric orthopedic surgeons and their patients. Our dedication to the pediatric orthopedic community is evidenced by our leading support of the five major pediatric orthopedic surgical societies that conduct pediatric clinical education and research. In 2015, we conducted more than 240 training workshops focused on fellows and surgeons early in their careers, which was more than double the number of workshops we held in 2014. We are the major sponsor of CME courses in pediatric spine and pediatric orthopedics. We believe collaborating with pediatric orthopedic surgeons has helped to promote familiarity with our products and loyalty among fellows and surgeons early in their careers.

- *Comprehensive Portfolio of Innovative Orthopedic Products Designed Specifically for Children.* We have developed the only comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions. Currently, we market 17 surgical systems and more than 2,500 stock keeping units, or SKUs, that address pediatric trauma and deformity, complex spine and ACL reconstruction procedures. Our products include features that provide specific advantages for pediatric orthopedic surgeons and their patients, such as surgical instrumentation specifically designed for use in children, proper anatomical sizes and contouring, and proprietary designs that address the unique skeletal anatomy and physiology of a growing child. Our broad product offering has made us, within the three categories of the market that we currently serve, the only provider of comprehensive solutions to pediatric orthopedic surgeons, who for the most part are generalists performing a wide range of orthopedic surgeries. Since inception, our average clearance time with the FDA has been 74 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is due in part to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children.
- *Scalable Business Model.* Our ability to identify and respond quickly to the needs of pediatric orthopedic surgeons and their patients is central to our culture and critical to our continued success. Within the United States, we have relationships with 34 independent sales agencies employing more than 90 sales representatives specifically focused on pediatric orthopedics. Outside of the United States, we work with 21 independent distributors in 29 countries. We estimate that 62% of U.S. pediatric trauma and deformity and complex spine procedures in 2015 were performed in only 268 hospitals. We believe that this high concentration of procedures and our focused sales organization will enable us to address the pediatric orthopedic surgery market in a capital-efficient manner. In addition, we believe our exclusive focus on hospitals that perform pediatric orthopedic surgery will allow us to grow our revenue while leveraging investment in a smaller number of consigned implant and instrument sets. As we continue to broaden our product offering, we believe the scalability of our business model will allow us simultaneously to increase our reach, deepen our relationships with pediatric orthopedic surgeons and help us to achieve significant returns on our investments in implant and instrument sets, product development and commercial infrastructure.
- *Unique Culture: A Different Kind of Orthopedic Company.* We have established a results-oriented, people-focused corporate culture dedicated to improving the lives of children with orthopedic conditions. Our senior management team provides engaging leadership and believes that the only hierarchy is that of good ideas, which can come from everywhere in our company. Our three product categories are each led by a vice president, who chairs a business team composed of representatives from research and development, quality and regulatory, operations, sales and finance functions. These teams meet frequently and make decisions regarding new products, inventory builds and promotional activities, thus enhancing our agility and the speed of decision making. We believe this culture allows

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us to attract and retain talented, high performing professionals. We believe our focus and commitment to pediatric orthopedics has also enhanced our reputation among pediatric orthopedic surgeons as the only diversified orthopedic company focused on their field.

We believe that our exclusive focus on pediatric orthopedic surgery, our collaborations with surgeons, our comprehensive product portfolio, our scalable business model and our engaging culture are all sources of significant competitive advantage. We believe these sources of competitive advantage provide us with the means to expand and defend our position as category leader and constitute barriers to entry that would require significant time, focus, and investment for a competitor to overcome.

### **Our Strategy**

Our goal is to continue to enhance our leadership in the pediatric orthopedic surgery market and thereby improve the lives of children with orthopedic conditions. To achieve this goal, we have implemented a strategy that has five elements:

- *Increase Investment in Consigned Implant and Instrument Sets to Accelerate Revenue Growth.* We intend to increase our investment in implant and instrument sets consigned to hospitals in the United States and select international markets to satisfy market demand and accelerate our product sales worldwide. Due to the high concentration of pediatric orthopedic surgeons in comparatively few hospitals, we believe we can accelerate the penetration of our addressable market efficiently.
- *Capitalize on Our Efficient Product Development Process to Expand Our Innovative Products.* We have a track record of introducing innovative products that meet the clinical needs of pediatric orthopedic surgeons and their patients. We believe many of these products are becoming the standard of care in pediatric orthopedic surgery, and we intend to increase our investment in research and development of new products. We aim to surround our customers with all the surgical systems they need to do their work, and our product pipeline includes a number of new systems and product line extensions. We aspire to launch one new surgical system and multiple product line extensions each year for the foreseeable future. We intend to leverage our market knowledge, the experience of our Surgeon Advisory Board and our relationships with leading pediatric orthopedic surgeons to continue developing innovative technologies and bringing them to market quickly. We believe broadening our product offering will strengthen our position as the comprehensive solution provider for pediatric orthopedic surgeons, deepen our relationships with existing customers, lead to the acquisition of new customers and enhance our reputation.
- *Strengthen Our Global Sales and Distribution Infrastructure.* We believe there is significant opportunity for us to leverage our exclusive focus on pediatric orthopedic surgery and expand our market penetration and share. We intend to continue investing in our global sales and distribution organization by increasing the number and upgrading the quality of our independent sales agencies and distributors through recruitment, adding clinical and sales training programs and, starting in 2016, supplementing our use of independent distributors with a direct international sales program in select markets. We are also developing a distribution organization focused on sports medicine physicians practicing at ambulatory surgery centers, representing a new sales channel for our ACL reconstruction system. Many experienced sales agencies and distributors have been impacted by ongoing consolidation in the orthopedic industry and, as a result, we believe are eager to adopt new product lines like ours. We believe these continued investments will strengthen our relationships with pediatric orthopedic surgeons, expand our presence in the hospitals where pediatric orthopedic surgery is performed and leverage our proprietary technologies to enhance the field of pediatric orthopedic surgery.
- *Deepen Our Partnerships With Pediatric Orthopedic Surgeons Through Clinical Education and Research.* We want pediatric orthopedic surgeons to view us as their partner in advancing the field of pediatric orthopedic surgery. Beyond working with them to develop innovative products, we intend to deepen our partnership with surgeons by leveraging the

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experience of our senior management team, including our CMO, to expand our clinical education programs and partnerships with teaching hospitals, sponsor surgical workshops for residents and fellows and support worthwhile clinical research projects. We believe our commitment to clinical education and research enables us to advance the practice of pediatric orthopedic surgery and provides surgeons with access to sophisticated training in pediatric orthopedics that is not available through traditional residents' training programs. We believe these efforts will continue to promote familiarity with our products and loyalty among fellows and young surgeons and generate new product ideas that will contribute to growth, enhance our competitive position and expand our market opportunity.



- *Continue to Develop an Engaging Culture of Continuous Improvement.* We believe that culture can be a company's most powerful source of competitive advantage. Cultures are unique, cannot be reverse-engineered and are impossible to duplicate. We have established a corporate culture that is results-oriented and people-focused. It is built on the cause of improving the lives of children with orthopedic conditions. We believe our higher corporate purpose captures the hearts and minds of our employees and empowers them to be committed to doing everything better, faster and at lower cost. We intend to continue developing this engaging culture of continuous improvement with the goal of building a different kind of orthopedic company: one that is committed to children, works with distributors as partners and aims to address the market's unmet needs.

### Our Product Portfolio








We have developed the only comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions within the three categories of the pediatric orthopedic market that we currently serve. Currently, we market 17 surgical systems that address pediatric trauma and deformity, complex spine and ACL reconstruction/other procedures. Many of our products are available in a variety of sizes and configurations to address a wide range of patient conditions and surgical requirements. These surgical systems are summarized below.

#### Trauma and Deformity



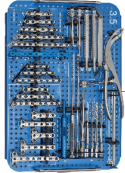

Our trauma and deformity product line includes implants and bone fixation devices for the femur, tibia and upper extremities. Our global revenue from this category for the year ended December 31, 2015 was \$22.5 million, or 73% of total revenue, which represented growth of 16% over the prior year.

Selected Product		Description	Region	Launched
3.0/3.5mm and 4.0mm Cannulated Screw Systems		Ideally suited for pediatric trauma and deformity applications. These screws are self-tapping, self-drilling and utilize threaded guide pins to guide screw placement.	U.S. International	2008 2011
7.0mm Cannulated Screw System		Available in multiple lengths and thread patterns, our 7.0mm cannulated screws are ideally suited for pediatric applications when treating a condition known as Slipped Capital Femoral Epiphysis. These screws are self-tapping, self-drilling and utilize threaded guide pins to guide screw placement.	U.S. International	2008 2011

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Selected Product		Description	Region	Launched
Locking Cannulated Blade Plates		Includes implants and instruments, designed for precision and simplicity. Offers comprehensive treatment options for hip deformity and fixed flexion deformities of the knee. This system provides enhanced fixation in bone using locking screws in the proximal and distal fragments, and restores the mechanical axis of the lower limb through the use of multiple offsets.	U.S. International	2012 2013
Locking Proximal Femur Plates		A comprehensive treatment option for hip deformity and trauma of the hip and proximal femur. Three converging cannulated screws form a proximal cluster allowing accurate placement and stable fixation. Multiple offset choices provide reproducible restoration of the mechanical axis of the lower limb.	U.S. International	2012 2013
PediFlex Flexible Nailing System		Indicated for the treatment of long bone fractures of the femur, tibia, humerus, radius, ulna and fibula. We believe the use of this system is safe, minimally invasive and associated with few complications.	U.S. International	2009 2012
PediLoc Extension Osteotomy System		Used to treat knee deformities, this system is pre-counterbored to minimize the need for plate bending and contouring during surgery and designed to allow locking screws to be placed in the distal bone segment at an angle parallel to the distal femoral growth plates.	U.S. International	2009 2012
PediLoc Femur Locking Plate System		Indicated for the treatment of pediatric femur fractures and osteotomies; eliminates the need for bending and contouring during surgery while also improving fixation. This system allows surgeons to address patients with varying skeletal maturity levels by utilizing accurately-fitted femur plates.	U.S. International	2009 2012
PediLoc Tibia Locking Plate Systems		Anatomically designed plates indicated for the treatment of pediatric tibia fractures and osteotomies; designed to achieve optimal fixation while avoiding damage to the growth plates.	U.S. International	2009 2012
PediNail Intramedullary Nail System		Allows for lateral trochanteric entry points to facilitate simplified procedures and reduce danger of damaging blood vessels near the piriformis fossa. The product's proximal lateral bend accommodates its lateral trochanteric entry point and its smaller diameter that allows for easier insertion without the need for excessive reaming, or widening, of the canal.	U.S. International	2010 2012

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Selected Product		Description	Region	Launched
PediPlates System		Utilizes growth plate tethering technique that does not disrupt the integrity of the growth plate. It features simple plate and screw constructs that span and restrain the growth plate, thus inhibiting bone growth where applied. The stainless steel design provides resistance to breakage and ease of removal.	U.S. International	2009 2012
PediPlates Delta System		Utilizes a physal tethering technique that does not disrupt the integrity of the growth plate. It features simple plate and screw constructs that span and constrain the growth plate, thus inhibiting bone growth applied. The stainless steel design provides resistance to breakage and ease of removal. It allows for maximal screw angulation of both screws offering a solution for larger patients with a condition known as Adolescent Blount's Disease.	U.S. International	2015 2015
PediFrag System		Combines three sets (mini-frag, small-frag and cannulated screws) into one system. It also features 2.7mm locking compression plates and is ideally suited to treat pediatric upper extremity fractures.	U.S. International	2014 2014
Scwire System		Offers percutaneous application, reverse cutting flutes, simple instrumentation, cut-to-length capability and a compression nut providing the ability to compress fragments after drilling. Its dual thread design and accompanying compression nut are designed to stabilize comminuted displaced small bone fractures of the upper and lower extremities, making it a simple and effective solution for small fracture fixation.	U.S.	2008

### Complex Spine

Our complex spine product category includes our RESPONSE systems for treating spinal deformity in children. Our global revenue from this category for the year ended December 31, 2015 was \$7.4 million, or 24% of total revenue, which represented growth of 109% over the prior year.



Selected Product		Description	Region	Launched
RESPONSE 5.5mm Spine System		Offers an ergonomic, technologically advanced system of instruments and implants to treat spinal deformity. Incorporates an innovative, low profile pedicle screw design and proprietary set screw thread design for improved fixation and reduced potential for cross threading. Its versatile reduction and de-rotation capabilities enable surgeons to perform their technique of choice.	U.S. International	2013 2014

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Selected Product		Description	Region	Launched
RESPONSE 5.5/6.0mm Spine System		Offers all of the benefits of the RESPONSE 5.5mm Spine system but allows the surgeon to fit both 5.5mm and 6.0mm titanium or cobalt chromium spinal rods.	U.S.	2015

### ACL Reconstruction/Other

Our ACL reconstruction/other product category primarily includes our ACL Reconstruction system and our spica casting tables. Our global revenue from this category for the year ended December 31, 2015 was \$1.1 million, or 3% of total revenue, which represented growth of 35% over the prior year.

Selected Product		Description	Region	Launched
ACL Reconstruction System		Features intuitive, easy to use instrumentation that provides options for reconstruction, including Iliotibial Band Reconstruction Instrumentation and versatile drilling instrumentation. This system uses a safe and anatomic drilling technique to help re-create the native ACL footprint.	U.S. International	2014 2015
Spica Table		Offers surgeons a properly engineered device for casting procedures. This radiolucent, lightweight, and durable device enables the user to carefully hold hip or femur reduction and take fluoroscopic images of the patient before application of the hip spica cast.	U.S. International	2011 2012

### Product Pipeline

We have three product development objectives: (i) develop innovative new systems that enable new surgical procedures, advance the field of pediatric orthopedics and allow us to focus on categories of the pediatric orthopedic market we are not currently addressing such as foot and ankle, hand and wrist, clavicle, pelvis and other sports-related injuries; (ii) build-out our portfolio of current products with line extensions that allow these systems to be used in more types of surgeries; and (iii) make improvements to our current implants and instruments that reduce their cost and improve their effectiveness. We have a large number of new product ideas under development, and we aspire to launch one new surgical system and multiple line extensions and product improvements every year.

An example of a planned new system and a planned line extension are highlighted below.

#### BandLoc

To complement our spine system, we are launching the BandLoc polyester band. This product will be used in patients with poor bone quality, often associated with neuromuscular scoliosis, where access to the pedicles is reduced because bones are too brittle, small or deformed for proper screw fixation. This product builds upon our expertise developing systems for patients with cerebral palsy. BandLoc will be used in conjunction with, or as a replacement for, pedicle screws. BandLoc complements our RESPONSE Spinal Deformity system and is compatible with most third-party spine systems on the market.

#### PediLoc Infant Locking Proximal Femur Plate

Complementing our current PediLoc Locking Proximal Femur system, we are introducing an Infant Locking Proximal Femur Plate that will be available in various lengths with 3.5mm convergent solid and cannulated screws. This product will increase the number of patients we can treat with our Locking Proximal Femur Plate system.

## **Research and Product Development**

We seek to leverage our considerable experience in pediatric orthopedics to develop innovative implants and instruments that serve the unmet needs of pediatric orthopedic surgeons and their patients. Some of our product designs leverage our exclusive rights to the Hamann-Todd Collection of the Cleveland Natural History Museum, the world's largest pediatric osteological collection.

We have made significant investments in product development personnel and infrastructure, and we believe that ongoing research and development efforts are essential to our success. Our culture of continuous improvement challenges us to develop better products efficiently and at lower cost. New products are developed by teams of engineers, commercial personnel and surgeon advisors, who work closely together through the design, prototype and market-testing phases of a product's development.

Our clinical and regulatory affairs personnel support our product design teams to facilitate regulatory clearances and market registrations. Since inception, our average clearance time with the FDA has been 74 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is in part due to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children.

Our research and development expenses were \$1.7 million and \$1.8 million for the years ended December 31, 2014 and December 31, 2015, respectively.

## **Sales and Marketing**

We believe we are the only orthopedic company with a robust pediatric-focused infrastructure, including a dedicated global commercial organization. As of December 31, 2015, our U.S. sales organization consisted of 34 independent sales agencies employing more than 90 sales representatives specifically focused on pediatrics. Increasingly, these sales agencies are making us the anchor line in their businesses or representing us exclusively. Sales from such agencies represented 81% of our U.S. revenue in 2015.

Outside of the United States, our sales organization consisted of 21 independent stocking distributors in 29 countries, including the largest markets in the European Union, Latin America and the Middle East, as well as South Africa, Australia and Japan. We believe our distributors are well regarded by pediatric orthopedic surgeons in their respective markets. To support our international distribution organization, we have hired a number of regional market managers, whose product and clinical expertise deepens our relationships with both surgeons and our distributors. In the near term, we expect to selectively expand the number of international markets we serve, as well as to deepen our penetration of important existing markets such as Brazil and Japan. Starting in 2016, we intend to supplement our use of independent distributors with a direct international sales program in select markets.

We have developed intensive training programs for our global sales organization. We expect our sales agencies and distributors to continue to deepen their knowledge of pediatric clinical conditions, surgical procedures and our products, thus increasing their effectiveness. Our domestic and international sales representatives are usually present in the operating room during surgeries in which our products are used. We believe the clinical expertise of our global sales organization and their presence both in and out of the operating room will enable them to increase pediatric orthopedic surgeons' confidence in using our products, deepen their relationships with existing customers and lead to the acquisition of new customers.

## **Global Pediatric Orthopedic Surgeon Involvement, Education and Training**

We are dedicated to the cause of improving the lives of children with orthopedic conditions. We want pediatric orthopedic surgeons throughout the world to view us as their partner in advancing their field. Therefore, we utilize surgeon input on product development and clinical education. These efforts are aided by our CMO, a highly respected former pediatric orthopedic surgeon, and the Surgeon Advisory Board he chairs. Our entire organization, including our senior executive team and sales representatives, maintains an extensive network of contacts with pediatric orthopedic surgeons. These relationships help us understand clinical needs, respond quickly to customer ideas and support new developments in the field of pediatric orthopedics.



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We are committed to advancing pediatric orthopedic care by supporting clinical education. We support local, regional and national educational courses, intensive hands-on training programs and product-based workshops that enable surgeons to practice surgical procedures using our products. In 2015, we conducted more than 240 training workshops focused on fellows and surgeons early in their careers, which was more than double the number of workshops we held in 2014. We are also the major sponsor of CME courses in pediatric spine and pediatric orthopedics. In 2015, we sponsored the First Annual Pediatric Spine Symposium, which was held at The University of Central Florida College of Medicine Bioskills Lab in Orlando, Florida, and we are preparing the First Annual Pediatric Fellows Orthopedic Surgical Principles Course to be conducted at The Medical Education and Research Institute in Memphis, Tennessee. We have a growing commitment to the clinical research performed by surgeons. This commitment ranges from providing our products for clinical outcome studies to providing advanced research grants.

Cumulatively, we are the largest financial contributor to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research: the Pediatric Orthopedic Society of North America, the International Pediatric Orthopedic Symposium, the European Pediatric Orthopedic Society, the American Academy for Cerebral Palsy and Developmental Medicine and the Pediatric Research in Sports Medicine Society. Additionally, we are a sponsor of the two major spine deformity organizations, the Scoliosis Research Society and the International Meeting on Advanced Spine Techniques. We are also the founding and leading sponsor of the Pediatric Research in Sports Medicine Society. Our support of these organizations demonstrates our commitment to the clinical training and research these organizations sponsor. We believe this support enhances our reputation as the category leader in pediatric orthopedics.

### **Manufacturing and Suppliers**

Our products are manufactured to our specifications by third-party suppliers who meet our manufacturer qualification standards. Our third-party manufacturers meet FDA and other country-specific quality standards, supported by our internal specifications and procedures. We believe these manufacturing relationships allow us to work with suppliers who have well-developed specialized competencies, minimize our capital investment, control costs and shorten cycle times, all of which we believe allow us to compete with larger volume manufacturers of orthopedic implants. We work closely with our suppliers with a goal of ensuring our inventory needs are met while maintaining high quality and reliability.

All of our device contract manufacturers are required to be ISO 13485 certified and are registered establishments with the FDA. Our internal quality management group conducts comprehensive on-site inspection audits of our suppliers to ensure they meet FDA and other country-specific requirements, as necessary. In addition, we and our suppliers are subject to periodic unannounced inspections by U.S. and international regulatory authorities to ensure compliance with quality regulations.

We do not have long-term supply contracts, nor do our suppliers require guaranteed minimum purchases. In most cases, we have redundant manufacturing capabilities for each of our products. To date, we have not experienced any difficulty obtaining the materials necessary to meet demand for our products, and we believe manufacturing capacity is sufficient to meet global market demand for our products for the foreseeable future.

### **Intellectual Property**

Our success depends upon our ability to protect our intellectual property. We rely on a combination of intellectual property rights, including patents, trade secrets, copyrights and trademarks, as well as customary confidentiality and other contractual protections. We own numerous issued patents and pending patent applications that relate to our technology. As of December 31, 2015, we owned seven issued U.S. patents and six issued foreign patents and we had five pending U.S. patent applications and nine foreign patent applications. As of December 31, 2015, two of our U.S. issued patents have pending continuation or divisional applications in process which may provide additional intellectual property protection if issued as U.S. patents. Our issued U.S. patents expire between 2024 and 2032, subject to payment of required maintenance fees, annuities and other charges. As of December 31, 2015, we owned

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nine U.S. trademark registrations and two pending U.S. trademark applications, as well as 15 registrations and three pending applications in other jurisdictions worldwide.

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

### **Competition**

The orthopedic industry is competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Our currently marketed products are, and any future products we commercialize will be, subject to competition. We believe the principal competitive factors in our markets include:

- improved outcomes for medical conditions;
- acceptance by orthopedic surgeons;
- ease of use and reliability;
- acceptance by the patient community;
- product price;
- availability of implant-specific instrument sets;
- effective marketing and distribution; and
- speed to market.

We have competitors in each of our three product categories, including the DePuy Synthes Companies (a subsidiary of Johnson & Johnson), Medtronic plc and Smith & Nephew plc. We believe we have the broadest product offering across these categories relative to these competitors. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, are cost effective and are safe and effective.

### **Government Regulation**

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices under the FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA clearance or approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

#### *FDA Premarket Clearance and Approval Requirements*

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or PMA approval. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed

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to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed products are Class II or unclassified devices subject to 510(k) clearance.

### *510(k) Marketing Clearance Pathway*

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from nine to twelve months, but may take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a de novo classification or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for every change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

The FDA is currently considering proposals to reform its 510(k) marketing clearance process, and such proposals could include increased requirements for clinical data and a longer review period. Specifically, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the 510(k) program, and in July 2014, published a new guidance document governing the review process for the clearance of medical

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devices. Specifically, the FDA has adopted new practices related to the acceptance of 510(k) applications which could place a higher standard on data and evidence provided to the FDA and a reduced ability to definitionally (i.e. same intended use, same technological characteristics) consider other devices as potential predicates. The FDA intends these reform actions to improve the efficiency and transparency of the 510(k) clearance process, as well as bolster patient safety. In addition, as part of FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several “Medical Device Regulatory Improvements” and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval.

### *Post-market Regulation*

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with healthcare customers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that claim includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

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- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

### *Regulation of Medical Devices in the EEA*

There is currently no premarket government review of medical devices in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC). The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to

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satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and applicable European and International Organization for Standardization standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation (the Medical Devices Regulation). Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission's proposals. Under the revised proposals, only designated "special notified bodies" would be entitled to conduct conformity assessments of high-risk devices, such as active implantable devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group (MDCG), (a new, yet to be created, body chaired by the European Commission, and representatives of Member States) for an opinion. These new procedures may result in the re-assessment of our existing medical devices, or a longer or more burdensome assessment of our new products.

If finally adopted, the Medical Devices Regulation is expected to enter into force sometime in 2016 and become applicable three years thereafter. In its current form it would, among other things, also impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance, and provide for more strict clinical evidence requirements.

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing;
- product standards;

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- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

We anticipate that the EU Medical Devices Regulation will enter into force in 2016 and become applicable three years thereafter. We expect this revised regulation to include further controls and requirements on the following activities:

- high level of request for premarket clinical evidence for high risk devices;
- increased scrutiny of technical files for implantable devices;
- monitoring of notified bodies, by independent auditors;
- increased requirements regarding vigilance and product traceability (specifically related to labeling requirements); and
- increased regulation for non-traditional roles such as importer and distributor.

### *Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws*

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the DHHS issued regulations in July 1991, which



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the Department has referred to as “safe harbors.” These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute can result in imprisonment, exclusion from Medicare, Medicaid or other governmental programs, as well as civil and criminal penalties, including criminal fines of up to \$5,000 and imprisonment of up to five years. Violations are subject to civil monetary penalties up to \$50,000 for each violation, plus up to three times remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act of up to \$11,000 for each claim submitted, plus up to three times the amounts paid for such claims. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate “qui tam” whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines ranging from \$5,500 to \$11,000 for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009, or FERA, was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program



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that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

HIPAA also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1 million per year for "knowing failures." Manufacturers must submit reports by the 90<sup>th</sup> day of each calendar year. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

### *Data Privacy and Security Laws*

We may also become subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by HITECH, in the United States.

Under HIPAA, the DHHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers and their business associates. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA violations carry civil and criminal penalties, including civil monetary penalties up to \$50,000 per violation, not to exceed \$1.5 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to \$250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages up to \$25,000 per violation on behalf of residents of his or her state.

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data

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in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the EU Data Protection Directive (95/46/EC) regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. As each, EU Member State has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ significantly by jurisdiction. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a legal grounds set out in the local laws, and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

Local laws are amended from time to time, and guidance is issued frequently by regulators. Any changes in law and new guidance may impact, and require changes to, our current operations. Additionally, on January 25, 2012, the European Commission published its draft EU General Data Protection Regulation. On March 12, 2014, the European Parliament formally passed a revised proposal of the Regulation, and the Council of the European Union published its general approach on June 15, 2015. Trilogue discussion between the European Commission, European Parliament and Council of the European Union are currently ongoing and are expected to come into force by 2018. The current form of the Regulation proposes significant changes to the EU data protection regime. Unlike the E-Privacy and Data Protection Directives, the Regulation has direct effect in each EU Member State, without the need for further enactment. When implemented, the Regulation will likely strengthen individuals' rights and impose stricter requirements on companies processing personal data. Significant changes in the current draft of the Regulation include: (i) the need for consent to processing to always be explicit; (ii) increased measures to provide information regarding the processing of personal data to individuals in a concise, transparent, intelligible and easily accessible form; (iii) tougher sanctions (as currently drafted, the applicable data protection authority may be able to impose a fine of up to EUR 20 million or four percent of annual worldwide turnover, whichever is greater); (iv) increased rights of the data subject and a requirement to notify the data protection authority of data breaches; and (v) companies will have to appoint a data protection officer if they are handling significant amounts of sensitive data.

### *Healthcare Reform*

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical

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device manufacturers significantly. The Affordable Care Act imposed, among other things, a new federal excise tax on the sale of certain medical devices (which has been suspended until December 31, 2017 and absent further legislative action will be reinstated starting January 1, 2018), provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

### *Anti-Bribery and Corruption Laws*

Our U.S. operations are subject to the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

### **Coverage and Reimbursement**

In the United States, our currently approved products are commonly treated as general supplies utilized in orthopedic surgery and if covered by third-party payors, are paid for as part of the surgical procedure. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies.

Based on our experience to date, third party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although

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no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including each payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third party payors.

The CMS is responsible for administering the Medicare program and sets coverage and reimbursement policies for the Medicare program in the United States. CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make coverage and payment decisions. Medicaid programs are funded by both federal and state governments, and may vary from state to state and from year to year and will likely play an even larger role in healthcare funding pursuant to the Affordable Care Act.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology, or CPT, code. To receive payment, healthcare practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. All third party reimbursement programs are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions prior to major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering healthcare.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third party payors, that an adequate level of reimbursement will be available or that the third party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an

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additional layer of clearance requirement. Specifically, Australia now requires clinical data for clearance and reimbursement be in the form of prospective, multi-center studies, a high bar not previously applied. In addition, in France, certain innovative devices have been identified as needing to provide clinical evidence to support a “mark-specific” reimbursement.

It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products.

### **Employees**

As of December 31, 2015, we employed 69 full-time employees. Of our full-time employees, 14% were engaged in research and development and 49% were engaged in sales and marketing. None of our employees are subject to a collective bargaining agreement, and we consider our employee relations to be good.

### **Facilities**

We own and occupy approximately 13,000 square feet of office space in Warsaw, Indiana. We believe our current facilities are suitable and adequate to meet our current needs. We may add new facilities or expand existing facilities as we add employees, and we believe suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

### **Legal Proceedings**

From time to time, we are involved in various legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results or financial condition.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors, including their age, as of December 31, 2015:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Executive Officers</b>		
Mark C. Throdahl	64	President, Chief Executive Officer and Director
Fred L. Hite	48	Chief Financial Officer and Director
David R. Bailey	36	Executive Vice President
Gregory A. Odle	46	Executive Vice President
Peter F. Armstrong, M.D.	69	Chief Medical Officer
Daniel J. Gerritzen	46	General Counsel and Vice President of Legal and Human Resources
<b>Non-Employee Directors</b>		
Terry D. Schlotterback	60	Chairman of the Board of Directors
Bernie B. Berry, III	63	Director
Bryan W. Hughes	38	Director
Marie C. Infante	66	Director
Alan Kozlowski	52	Director
Oscar Moralez	53	Director
Peter J. Munson	49	Director
David R. Pelizzon	59	Director
Kevin L. Unger	44	Director

### Executive Officers

*Mark C. Throdahl* has served as our President and Chief Executive Officer since January 2011 and as a director since 2009. Prior to joining our company, Mr. Throdahl served from 2008 to 2009 as a Group President of Zimmer Holdings, Inc., a worldwide leader in orthopedic implants. Mr. Throdahl previously served from 2001 to 2007 as the Chief Executive Officer and Director of Consort Medical plc in London, United Kingdom. During a 13 year career at Becton Dickinson & Co., he served as Senior Vice President of the Drug Delivery sector and President of Nippon Becton Dickinson in Tokyo. Mr. Throdahl began his career at Mallinckrodt, Inc. Mr. Throdahl is a graduate of Princeton University and earned an MBA from Harvard Business School. We believe Mr. Throdahl's leadership of both large organizations and growing businesses qualifies him to serve on our board of directors.

*Fred L. Hite* has served as our Chief Financial Officer since February 2015 and as a director since August 2015. Prior to joining our company, from 2004 through 2014, Mr. Hite served as the Chief Financial Officer and Investor Relations Officer of Symmetry Medical Inc., or Symmetry, a company previously listed on the New York Stock Exchange. See "— Other Information." Prior to joining Symmetry, Mr. Hite spent 13 years with General Electric Corporation in a variety of financial positions and areas including commercial, manufacturing, sourcing and services. Mr. Hite earned a Bachelor of Science in Finance from the Indiana University Kelley School of Business. We believe Mr. Hite's financial acumen and public company management experience qualify him to serve on our board of directors.

*David R. Bailey* joined our company in 2007 and has served as our Executive Vice President since 2009. Mr. Bailey also served as a member of our board of directors from 2007 to 2013. Prior to joining us, Mr. Bailey worked as a sales representative and distributor for Smith & Nephew plc. Mr. Bailey earned a Bachelor of Science in Sales and Sales Management from Purdue University.

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*Gregory A. Odle* joined our company in 2007 and has served as our Executive Vice President since 2011. Mr. Odle also served as a member of our board of directors from 2007 to 2013. Prior to joining us, Mr. Odle held various sales roles for Smith & Nephew plc, ultimately becoming the District Manager for Indiana and Kentucky. Mr. Odle earned a Bachelor of Science in Marketing from the Indiana University Kelley School of Business.

*Peter F. Armstrong, M.D.* has served as our Chief Medical Officer since January 2013. He served as a member of our board of directors from September 2009 to January 2013. From 1991 to 2000, he served as the Chief of Staff of Shriners Hospitals for Children Intermountain in Salt Lake City, Utah. In 2000, Dr. Armstrong was selected as the Chief Medical Officer of the 22 Shriners Hospitals, where he served until June 2012 when he became the Chief Medical Officer — Emeritus, a position in which he continues to serve. Dr. Armstrong received his medical degree from the University of Western Ontario in 1972. He completed his orthopedic residency at the University of Toronto, followed by a pediatric orthopedic fellowship with Dr. Robert Salter at The Hospital for Sick Children in Toronto. Following his residency, Dr. Armstrong joined The Hospital for Sick Children, but first spent two years performing orthopedic research at the University of Pennsylvania. Dr. Armstrong is a fellow of the Royal College of Physicians and Surgeons of Canada.

*Daniel J. Gerritzen* has served as our General Counsel and Vice President of Legal and Human Resources since January 2009. Prior to joining our company, Mr. Gerritzen was a partner with Bingham Greenbaum Doll LLP, a law firm in Indianapolis, where he continues to serve as Of Counsel. Mr. Gerritzen spends substantially all of his time working for our company. Mr. Gerritzen earned a Bachelor of Science in Marketing and a JD from Indiana University.

### **Non-Employee Directors**

*Terry D. Schlotterback* has served as a director since 2009 and as Chairman of the board of directors since September 2013. Mr. Schlotterback was also employed by us from February 2009 to February 2010. Prior to joining our board of directors, Mr. Schlotterback worked for Zimmer from 1982 to 1992 and from 1996 to 2006, where he served in various leadership positions in sales, marketing and research and development, including as President of the Trauma and Spinal divisions. Prior to joining Zimmer, Mr. Schlotterback served in senior management roles for Mitek Surgical Products from 1992 to 1995. Mr. Schlotterback is a founder of the Warsaw, Indiana chapter of VisionTech Angels, an investment group, and TDS Consulting, LLC, which provides consulting services to medical startup companies. Mr. Schlotterback earned a Bachelor of Science in Mechanical Engineering Technology from Purdue University. We believe Mr. Schlotterback's extensive experience in the medical device field qualifies him to serve on our board of directors.

*Bernie B. Berry, III* has served as a director since 2009. Mr. Berry is the former President and owner of Carr Metal Products, Inc., a precision sheet metal and plastic fabrications firm. Mr. Berry joined Carr in 1975 and was appointed its President in 1985. In 2006, Carr was acquired by Precimed Group, a supplier to the orthopedic industry. Mr. Berry is a graduate of Purdue University. We believe Mr. Berry's experience in growing businesses and product development, as well as his continuous involvement in the orthopedic industry, qualifies him to serve on our board of directors.

*Bryan W. Hughes* has served as a director since 2012. Mr. Hughes is the Director and Group Head of Medical Technology Investment Banking at P&M Corporate Finance, LLC, an investment bank providing merger and acquisition services to companies throughout North America and Europe, a position he has held since 2008. Mr. Hughes earned a B.B.A. with an emphasis in Finance and Accounting from the Stephen M. Ross School of Business at the University of Michigan. Mr. Hughes is a licensed securities representative, holding Series 7 and 63 registrations. We believe Mr. Hughes's experience advising private and public medical technology companies in strategic, financial and transaction related matters qualifies him to serve on our board of directors.

*Marie C. Infante* has served as a director since 2014. Ms. Infante currently serves as the Interim Director of Compliance for Avalon Healthcare, a position she has held since 2015, a Senior Advisor to Triple Tree Capital Partners, a position she has held since 2013, and as Senior Advisor for BDO Consulting Center for Healthcare Excellence & Innovation, a position she has held since 2013. From 2006 to 2013, she



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served as the Senior Vice President, Chief Compliance Officer and General Counsel for Healthcare Law for Golden Living. Her experience also includes 15 years as a clinical specialist in orthopedic nursing. Ms. Infante is a graduate of the University of Maryland, where she earned a Bachelor of Science in Nursing and a Master of Science. She also earned an MBA from Loyola University and a JD from the Catholic University of America. We believe Ms. Infante's clinical orthopedic experience and knowledge as a healthcare lawyer and compliance expert qualify her to serve on our board of directors.

*Alan Kozlowski* has served as a director since 2015. From 2007 to 2014, Mr. Kozlowski served as the President of Colson Group Holdings LLC, a group of medical companies that includes Acumed LLC, MicroAire Surgical Instruments LLC, OsteoMed LLC, Precision Edge Surgical Products Company LLC, Skeletal Kinetics LLC and Apex Tools and Orthopedics Company. Prior to this role, Mr. Kozlowski served as the President of Acumed LLC from 1999 to 2007 and the President of American Medical Instruments, Inc. from 1996 to 1999. He is a graduate of the University of Michigan, where he earned an MBA and a Bachelor of Science in Chemical Engineering. We believe Mr. Kozlowski's experience managing growing, profitable, global organizations within the medical device and orthopedic industries qualifies him to serve on our board of directors.

*Oscar Moralez* has served as a director since 2009. Mr. Moralez co-founded VisionTech Partners, LLC (formerly known as Stepstone Business Partners, LLC) in 2008. Today, he manages day-to-day operations at VisionTech, a position he has held since 2008. Prior to founding VisionTech, in 2002 Mr. Moralez founded BioStorage Technologies, Inc., and served as its Chief Operating Officer until December 2007. From 2000 to 2002, Mr. Moralez served as Director of Specialty Services at Covance Inc., and from 1998 to 2000, he served as General Manager of Frontline Laboratory Network. Mr. Moralez earned a Bachelor of Science in Medical Technology from the University of Texas, Southwestern Medical Center at Dallas and an MBA from the University of Colorado. He serves on the boards of Apricity LLC, and SonarMed Inc. We believe Mr. Moralez's experience in the life sciences industry qualifies him to serve on our board of directors.

*Peter J. Munson* has served as a director since 2014. Mr. Munson is a co-founder and Managing Director of Cardinal Equity Partners, LLC, a private equity firm, a position he has held since 2008. Mr. Munson serves as the Chairman of the Board of Directors of Contour Industries, Inc., and also serves on the Board of Directors of Williams Sound Corporation, LLC, ESSCO, Inc., and Motion Tech Automation, Inc., all of which are Cardinal portfolio businesses. Prior to founding Cardinal, Mr. Munson served as a Senior Vice President for JPMorgan Chase, N.A. from 1988 to 2008. Mr. Munson serves as the Vice Chairman of Educational Choice Trust, a privately funded school voucher program. Mr. Munson earned a Bachelor of Arts in Economics from DePauw University in 1988. We believe Mr. Munson's experience in and knowledge of finance, as well as his broad experience with growing companies, qualifies him to serve on our board of directors.

*David R. Pelizzon* has served as a director since 2011. Mr. Pelizzon is the President and Chief Executive Officer of Squadron, a position he has held since 2008. Prior to joining Squadron, Mr. Pelizzon was the Managing Director of Precision Edge Surgical Products Company from 2005 to 2008. Mr. Pelizzon is a retired U.S. Army officer who served nearly 30 years on active duty in airborne and special operations units. Mr. Pelizzon is a graduate of the U.S. Military Academy and earned advanced degrees from Harvard University and the U.S. Naval War College. We believe Mr. Pelizzon's leadership and management experience qualify him to serve on our board of directors.

*Kevin L. Unger* has served as a director since 2011. Mr. Unger is currently the Chief Executive Officer of Columbia Nutritional, LLC, a nutritional supplement manufacturing company, a position he has held since 2015. He served as the Chief Executive Officer of Intrinsic Healthcare Inc. from 2011 to 2015. Prior to founding Intrinsic, he served as the Global President of Orthofix International N.V., a spinal implant and biologics business, from 2009 to 2011. Mr. Unger held various roles for Stryker Corporation from 1994 to 2009, ultimately becoming a Vice President and General Manager in the MedSurg division. We believe Mr. Unger's experience as an operator of both small private companies and large public businesses, as well as his experience in the orthopedic industry, qualifies him to serve on our board of directors.



## **Other Information**

In 2007, while Mr. Hite served as the Senior Vice President and Chief Financial Officer of Symmetry, Symmetry discovered accounting irregularities at its Sheffield, United Kingdom operating unit. This resulted in a restatement of certain of Symmetry's financial reports and an SEC inquiry; however, there was no allegation that Mr. Hite knew of or participated in any of the wrongdoing at the U.K. subsidiary. In 2006, Mr. Hite received a written status report from Symmetry's internal auditor for submission to Symmetry's audit committee that claimed to have identified potential accounting issues at the U.K. subsidiary. Although Mr. Hite provided the report to Symmetry's controller and independent accounting firm, and discussed its contents with each of them and Symmetry's internal auditor, he did not provide the report to Symmetry's audit committee. Following the internal auditor's resignation, Mr. Hite hired a new internal auditor and directed her to focus on the issues at the U.K. subsidiary, expanded Symmetry's internal audit department and located one new member of such department at the U.K. subsidiary.

On January 30, 2012, without admitting or denying the findings therein, Symmetry and Mr. Hite consented to the entry of an order settling the matter in which the SEC found, among other things, that Mr. Hite's failure to deliver the report to Symmetry's audit committee circumvented Symmetry's internal accounting controls in violation of the Exchange Act and contributed to Symmetry's violation thereof. Pursuant to such order, Mr. Hite agreed to: (i) cease and desist from committing or causing any violation or future violations of Sections 13(b)(2)(B) and 13(b)(5) of the Exchange Act and Section 304(a) of the Sarbanes-Oxley Act; (ii) pay a civil monetary penalty; and (iii) reimburse Symmetry for incentive compensation received during the statutory time period established by Sarbanes-Oxley. There was no allegation that Mr. Hite knew of or participated in any of the wrongdoing at the U.K. subsidiary, and the board of Symmetry maintained its support for Mr. Hite, who continued to serve as the Senior Vice President and Chief Financial Officer of Symmetry until the December 2014 sale of the majority of Symmetry to a private equity firm.

## **Board Composition and Election of Directors**

### *Board Composition*

Our board of directors currently consists of eleven members, three of whom serve as directors pursuant to the board composition provisions of our amended and restated certificate of designations, preferences and rights of preferred stock, or the Preferred Stock Terms. The Preferred Stock Terms provide holders of our Series A Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect one member of our board of directors, which is currently Mr. Pelizzon, and provide holders of our Series B Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect two members of our board of directors, which are currently Ms. Infante and Mr. Kozlowski. We expect the Preferred Stock Terms to terminate concurrently with the conversion of all shares of our Series A Preferred Stock and Series B Preferred Stock into shares of our common stock immediately prior to the completion of this offering. Prior to this offering, we expect to enter into a stockholders agreement, or the Stockholders Agreement, which will provide current holders of our Series A Preferred Stock and Series B Preferred Stock with certain board representation rights following the completion of this offering. The Preferred Stock Terms and the Stockholders Agreement are further discussed in the "Certain Relationships and Related Person Transactions" section of this prospectus.

### *Director Independence*

Our board of directors currently consists of eleven members. Our board of directors has determined that Mr. Berry, Mr. Hughes, Ms. Infante, Mr. Kozlowski, Mr. Moralez, Mr. Munson, Mr. Schlotterback and Mr. Unger are independent directors in accordance with the listing requirements of NASDAQ. The NASDAQ independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with

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his exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

### *Classified Board of Directors*

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Effective upon the completion of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be      and      , and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be      and      , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be      and      , and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the completion of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. Our directors may be removed only for cause by the affirmative vote of the holders of at least 66 2/3% of our outstanding voting stock then entitled to vote in the election of directors.

### **Board Leadership Structure**

Our board of directors is currently led by its Chairman, Mr. Schlotterback. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of Chief Executive Officer and chairman of the board in recognition of the differences between the two roles. The Chief Executive Officer is responsible for setting the strategic direction for the company and the day-to-day leadership and performance of the company, while the chairman of the board of directors provides guidance to the Chief Executive Officer and presides over meetings of the full board of directors. We believe this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### **Role of Board in Risk Oversight Process**

Our board of directors has responsibility for the oversight of the company's risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand the company's risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk

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assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

### **Board Committees and Independence**

Our board of directors has established three standing committees — audit, compensation and corporate governance — each of which operates under a charter that has been approved by our board of directors.

Our board of directors has determined that all of the members of each of the board’s three standing committees are independent as defined under the rules of NASDAQ. In addition, all members of the audit committee meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

#### ***Audit Committee***

The audit committee’s main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee’s responsibilities include, among other things: appointing our independent registered public accounting firm; evaluating the qualifications, independence and performance of our independent registered public accounting firm; approving the audit and non-audit services to be performed by our independent registered public accounting firm; reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies; discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements; reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters; reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy; reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations; preparing the report that the SEC requires in our annual proxy statement; reviewing and approving any related person transactions and reviewing and monitoring compliance with our code of business conduct and ethics; and reviewing and evaluating, at least annually, the performance of the audit committee and its members, including compliance of the audit committee with its charter.

, and will serve as members of our audit committee after the completion of this offering. will serve as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and NASDAQ. Our board of directors has determined that is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations. Our board of directors has determined that each of , and is independent under the applicable rules of the SEC and NASDAQ. Upon the listing of our common stock on NASDAQ, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and NASDAQ.

#### ***Compensation Committee***

The compensation committee reviews and approves policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves the issuance of stock options and other awards under our equity incentive plan. The

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compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

, and will serve as members of our compensation committee after the completion of this offering. will serve as the chairperson of the committee. Our board has determined that each of , and is independent under the applicable rules and regulations of NASDAQ, is a “non-employee director” as defined in Rule 16b-3 under the Exchange Act and is an “outside director” as that term is defined in Section 162(m) of the Code. Upon the listing of our common stock on NASDAQ, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

### ***Corporate Governance Committee***

The corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters.

, and will serve as members of our corporate governance committee after the completion of this offering. will serve as the chairman of the committee. Our board has determined that each of , and is independent under the applicable rules and regulations of NASDAQ relating to corporate governance committee independence. Upon the listing of our common stock on NASDAQ, the corporate governance committee will operate under a written charter, which the corporate governance committee will review and evaluate at least annually.

### **Compensation Committee Interlocks and Insider Participation**

Prior to the completion of this offering, Mr. Schlotterback served as a member of our compensation committee. From February 2009 to February 2010, Mr. Schlotterback served as an officer of our company. None of the members of our compensation committee after the completion of this offering has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

### **Code of Business Conduct and Ethics**

Immediately prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer and principal financial and accounting officer. Our code of business conduct and ethics will be available under the Investor Relations — Corporate Governance section of our website at [www.orthopediatrics.com](http://www.orthopediatrics.com). In addition, we intend to post on our website all disclosures that are required by law or the listing standards of NASDAQ concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

**EXECUTIVE AND DIRECTOR COMPENSATION**

This section discusses the material components of the executive compensation program for our “named executive officers.” Our named executive officers and their positions for the year ended December 31, 2015 were as follows:

- Mark C. Throdahl, President and Chief Executive Officer;
- Fred L. Hite, Chief Financial Officer;
- David R. Bailey, Executive Vice President; and
- Gregory A. Odle, Executive Vice President.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt in connection with or following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

**Summary Compensation Table**

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2015.

<b>Name and Principal Position</b>	<b>Salary (\$)</b>	<b>Stock Awards (\$)<sup>(1)</sup></b>	<b>Non-Equity Incentive Plan Compensation (\$)<sup>(2)</sup></b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Mark C. Throdahl <i>President and Chief Executive Officer</i>	257,500	402,499	90,769	24,485 <sup>(3)</sup>	775,253
Fred L. Hite <sup>(4)</sup> <i>Chief Financial Officer</i>	229,167	255,834	80,781	—	565,782
David R. Bailey <i>Executive Vice President</i>	216,300	368,826	76,246	—	661,372
Gregory A. Odle <i>Executive Vice President</i>	216,300	360,859	76,246	—	653,405

(1) Amounts reflect the full grant-date fair value of restricted stock awards and stock options granted during 2015 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all restricted stock awards and stock options made to our named executive officers in Note 9 to our consolidated financial statements included elsewhere in this prospectus. There can be no assurance that unvested awards will vest (and, absent vesting, no value will be realized by the executive for the award).

(2) Amounts reflect bonuses paid with respect to 2015 services and the achievement of 70.5% of the performance criteria under our 2015 bonus plan.

(3) Amount reflects lodging expenses and travel expenses, which totaled \$19,525, incurred in connection with Mr. Throdahl’s travel between our headquarters in Warsaw, Indiana and his primary residence in St. Louis, Missouri, as well as membership to the Union League Club in Chicago, Illinois.

(4) Mr. Hite joined our company in February 2015. The salary reported reflects the pro rata portion of Mr. Hite’s annual salary of \$250,000 earned during 2015.

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The named executive officers receive a base salary pursuant to their employment agreements to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

The 2015 base salaries actually paid to our named executive officers are disclosed in the Summary Compensation Table above. For 2016, Messrs. Throdahl, Hite, Bailey and Odle received merit salary increases of 17%, 20%, 16% and 16%, respectively. The following table sets forth 2016 base salaries for each of our named executive officers.

Named Executive Officer	2016 Annual Base Salary
Mark C. Throdahl	\$ 300,000
Fred L. Hite	\$ 300,000
David R. Bailey	\$ 250,000
Gregory A. Odle	\$ 250,000

We expect that, following the completion of this offering, base salaries for the named executive officers will be reviewed periodically by the compensation committee, with adjustments expected to be made generally in accordance with the considerations described above and to maintain base salaries at competitive levels.

**2015 Bonus Plan**

Each of our named executive officers participated in our 2015 bonus plan pursuant to which each was eligible to receive a bonus based equally on our achievement of specified sales, EBITDA, cash flow and company objectives, as established by the compensation committee. For 2015, target bonuses were equal to 50% of each executive's annual base salary paid in 2015.

The actual annual cash bonuses paid for performance in 2015 are set forth in the Summary Compensation Table above in the column titled "Non-Equity Incentive Plan Compensation" and reflect achievement of 70.5% of the annual performance goals. We expect target bonus levels to remain at 50% of base salary under our 2016 bonus plan.

**Equity Compensation**

We currently maintain the Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, in order to provide additional incentives for our employees, directors, advisors and consultants and to enable us to obtain and retain the services of these individuals, which is essential to our long term success.

Certain of our named executive officers currently hold stock options and restricted stock in accordance with the 2007 Plan. Stock options typically vest upon grant. Restricted stock typically vests and the restrictions lapse upon the earlier of: (i) six months following an initial public offering; (ii) six years following the grant date or (iii) upon a change in control transaction (as defined in the 2007 Plan). The following table sets forth the restricted stock granted to our named executive officers in 2015.

Named Executive Officer	2015 Restricted Stock
Mark C. Throdahl	78,664
Fred L. Hite	50,000
David R. Bailey	72,083
Gregory A. Odle	70,526

In connection with this offering, we intend to adopt the 2016 Incentive Award Plan, referred to below as the 2016 Plan, in order to facilitate the grant of cash and equity incentives to our directors, employees (including our named executive officers) and consultants and certain of our affiliates and to enable us

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and certain of our affiliates to obtain and retain services of these individuals. We expect that the 2016 Plan will be effective on the date on which it is adopted by our board of directors, subject to approval of such plan by our stockholders. For additional information about the 2016 Plan, please see the section titled “Equity Incentive Plans” below.

### Other Elements of Compensation

**Retirement Plans.** We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. We expect that our named executive officers will be eligible to participate in the 401(k) plan on the same terms as other full-time employees.

**Health/Welfare Plans.** All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- short-term and long-term disability insurance; and
- life insurance.

We believe the perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

### No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers’ personal income taxes that may pertain to any of the compensation or perquisites paid or provided by us.

### Outstanding Equity Awards at 2015 Fiscal Year-End

The table below summarizes the aggregate stock option and restricted stock awards held by our named executive officers as of December 31, 2015. As described above in “— Equity Compensation,” stock options typically vest upon grant.

Name	Grant Date	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options (#) Exercisable <sup>(1)</sup>	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Unvested Restricted Shares at Fiscal Year End (#) <sup>(2)</sup>	Market Value of Unvested Restricted Shares at Fiscal Year End (\$) <sup>(3)</sup>
Mark C. Throdahl	1/29/2015	—	—	—	—	78,664	
	1/28/2014	—	—	—	—	2,584	
	1/28/2014	—	—	—	—	4,000	
	1/15/2014	—	—	—	—	100	
	12/31/2013	—	—	—	—	17,925	
	9/10/2013	600	—	20.75	9/10/2023	—	—
	6/30/2013	—	—	—	—	17,926	
	1/15/2013	—	—	—	—	5,000	
	12/31/2012	—	—	—	—	17,926	
	8/23/2012	600	—	20.75	8/23/2022	—	—
	6/30/2012	—	—	—	—	17,926	
	12/31/2011	—	—	—	—	17,926	
	8/3/2011	600	—	20.75	8/3/2021	—	—
	7/25/2011	—	—	—	—	53,778	
	9/2/2010	1,000	—	20.75	9/2/2020	—	—

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Name	Grant Date	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options (#) Exercisable <sup>(1)</sup>	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Unvested Restricted Shares at Fiscal Year End (#) <sup>(2)</sup>	Market Value of Unvested Restricted Shares at Fiscal Year End (\$) <sup>(3)</sup>
Fred L. Hite	2/13/2015	—	—	—	—	50,000	
David R. Bailey	1/29/2015	—	—	—	—	72,083	
	11/1/2014	—	—	—	—	8,333	
	5/1/2014	—	—	—	—	8,333	
	1/28/2014	—	—	—	—	2,171	
	1/28/2014	—	—	—	—	3,000	
	1/15/2014	—	—	—	—	100	
	11/1/2013	—	—	—	—	8,333	
	9/10/2013	600	—	20.75	9/10/2023	—	—
	5/1/2013	—	—	—	—	8,333	
	1/15/2013	—	—	—	—	1,000	
	11/1/2012	—	—	—	—	8,333	
	8/23/2012	600	—	20.75	8/23/2022	—	—
	5/1/2012	—	—	—	—	8,335	
	8/3/2011	600	—	20.75	8/3/2021	—	—
	9/2/2010	600	—	20.75	9/2/2020	—	—
	7/23/2010	7,200	—	20.75	7/23/2020	—	—
	7/9/2009	800	—	18.50	7/9/2019	—	—
	7/15/2007	22,560	—	6.25	7/15/2017	—	—
Gregory A. Odle	1/29/2015	—	—	—	—	70,526	
	11/1/2014	—	—	—	—	8,333	
	5/1/2014	—	—	—	—	8,333	
	1/28/2014	—	—	—	—	2,171	
	1/28/2014	—	—	—	—	3,000	
	1/15/2014	—	—	—	—	100	
	11/1/2013	—	—	—	—	8,333	
	9/10/2013	600	—	20.75	9/10/2023	—	—
	5/1/2013	—	—	—	—	8,333	
	1/15/2013	—	—	—	—	1,000	
	11/1/2012	—	—	—	—	8,333	
	8/23/2012	600	—	20.75	8/23/2022	—	—
	5/1/2012	—	—	—	—	8,335	
	8/3/2011	600	—	20.75	8/3/2021	—	—
	9/2/2010	600	—	20.75	9/2/2020	—	—
	7/23/2010	12,000	—	20.75	7/23/2020	—	—
	7/9/2009	800	—	18.50	7/9/2019	—	—
	9/11/2007	70,560	—	6.25	9/11/2017	—	—

(1) All stock options reflected were granted under the 2007 Plan and are fully vested.

(2) All restricted stock awards vest and the restrictions lapse upon the earlier of: (i) six months following an initial public offering; (ii) six years following the grant date or (iii) upon a change in control transaction (as defined in the 2007 Plan).

(3) The market value for our restricted stock is based on an assumed initial offering price of \$        per share, the midpoint of the price range set forth on the cover page of this prospectus.



## **Employment Agreements**

On July 31, 2014 (or in the case of Mr. Hite, February 1, 2015), we entered into substantially similar employment agreements with each of our named executive officers. The employment agreements provide for (i) a base salary; (ii) participation in our annual bonus plan and (iii) employee benefits and fringe benefits generally made available to all of our employees. The employment agreements will expire on July 31, 2017 (or in the case of Mr. Hite, February 1, 2017) and will automatically renew for successive one-year terms thereafter unless either party provides notice of their intent not to renew 30 days prior to the end of the term. The employment agreements also provide for the reimbursement of all reasonable business expenses incurred by a named executive officer on our behalf.

The employment agreements contain customary confidentiality, invention assignment and non-competition covenants. The non-competition covenant restricts our named executive officers during their respective employment term and for a period of one-year thereafter from soliciting our customers or employees and from competing with us anywhere where we or the named executive officer conducted business during the 12-month period immediately preceding such executive's termination.

Subject to continued compliance with the restrictive covenants and execution and non-revocation of a general release of claims in favor of us, the employment agreements also provide for certain severance payments and benefits if the executive's employment is terminated by us without "cause" or by the executive for "good reason" (each, as defined in the applicable agreement). In any such event, each executive is entitled to receive:

- 12 months of the executive's annual base salary then in effect, payable in 12 substantially equal monthly installments;
- a lump-sum payment in the amount equal to any unpaid bonus that was earned by the executive in any fiscal year ending prior to his termination;
- a lump-sum payment equal to the pro-rated value of any bonus earned upon the satisfaction of pre-established performance objectives, payable in the year following the year in which the services were performed when such bonuses are normally paid to employees; and
- up to 12 months of company-subsidized healthcare continuation coverage for the executive and his dependents.

## **Equity Incentive Plans**

### ***2007 Equity Incentive Plan***

The 2007 Plan was originally adopted by our board of directors and approved by our stockholders in November 2007. The 2007 Plan was subsequently amended in March 2008 and amended and restated in December 2012 and again in April 2014 and provides for the grant of stock options and restricted stock to our employees, directors, advisors and consultants or our qualifying subsidiaries, and such amendment and restatement was approved by our stockholders in December 2012. As of December 31, 2015, options to purchase 371,449 shares of common stock remained outstanding under the 2007 Plan.

The 2007 Plan will be terminated on, and we will not make any further awards under the 2007 Plan following, the date the 2016 Plan becomes effective. However, any outstanding awards granted under the 2007 Plan will remain outstanding, subject to the terms of our 2007 Plan and award agreements, until such outstanding awards vest and are exercised (as applicable) or until they terminate or expire by their terms. The material terms of the 2007 Plan are summarized below.

**Authorized Shares.** A maximum of 1,585,000 shares of our capital stock, whether common stock or preferred stock, may be issued under the 2007 Plan. If an award under the plan expires, terminates, is forfeited or is surrendered for cancellation, any shares subject to such award may, to the extent of such expiration, termination, forfeiture or cancellation, be used again for new grants under the 2007 Plan.

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*Plan Administration.* Our compensation committee currently administers the 2007 Plan and the awards granted thereunder. The plan administrator may select participants, grant awards, determine terms and conditions of such awards, interpret the terms of the 2007 Plan and any award agreements and adopt rules and procedures for the administration, interpretation and operation of the 2007 Plan.

*Awards.* The 2007 Plan provides for the discretionary grant of nonqualified stock options and restricted stock to our employees, directors, advisors and consultants.

- *Stock Options.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant, except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years. Vesting conditions are determined by the plan administrator.
- *Restricted Stock.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met. Conditions applicable to restricted stock may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

*Corporate Transactions.* The 2007 Plan provides that in the event of our dissolution, any restrictions on shares of restricted stock will lapse and each outstanding option will become exercisable in full before terminating. In the event of a merger, consolidation, share exchange or similar statutory transaction (i) each participant holding an option shall be entitled to receive in lieu of shares, the same stock, property or other consideration, calculated on a per share basis, as holders of shares were entitled to receive in connection with the transaction, such consideration the “transaction consideration,” and (ii) each share of restricted stock shall be converted into or exchanged for the transaction consideration, which shall be subject to the same restrictions to which the restricted stock was subject (unless the plan administrator accelerates the lapse of such restrictions). In connection with a “change of control” (as defined in the 2007 Plan), the plan administrator, in its sole discretion, may accelerate the vesting and expiration of any option or the lapse of restrictions on any restricted stock.

*Assignment and Transfers.* Except as provided in the 2007 Plan or as expressly authorized by the plan administrator, a participant may not transfer awards under the 2007 Plan other than by will, the laws of descent and distribution or pursuant to a qualified domestic relations order.

*Plan Amendment and Termination.* The 2007 Plan shall continue in effect for a term of ten years from the date of adoption. Notwithstanding the foregoing, our board of directors may at any time terminate, amend or modify the 2007 Plan, provided, however, no termination, amendment or modification shall affect any award without the consent of the participant or relevant transferee.

### **2016 Incentive Award Plan**

Prior to the completion of this offering, we expect to adopt, and our shareholders to approve, a new incentive award plan, or the 2016 Plan, the terms of which are still being determined.

### **Director Compensation**

In 2015, we granted restricted stock awards to certain of our non-employee directors. Restricted stock typically vests and the restrictions lapse upon the earlier of: (i) six months following an initial public offering; (ii) six years following the grant date or (iii) upon a change in control.

Our non-employee directors did not receive any cash compensation for their services in 2015. Each member of our board of directors is entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

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The following table sets forth information concerning the compensation of our directors during the year ended December 31, 2015. Messrs. Throdahl and Hite, each of whom is a named executive officer, do not receive additional compensation for their service as a director, and therefore are not included in the table below.

Name	Stock Awards (\$) <sup>(1)</sup>	Total (\$)
Terry D. Schlotterback	37,444	37,444
Bernie B. Berry, III	12,280	12,280
Bryan W. Hughes	3,070	3,070
Marie C. Infante	—	—
Alan Kozlowski	—	—
Oscar Moralez	12,280	12,280
Peter J. Munson	3,070	3,070
David R. Pelizzon <sup>(2)</sup>	—	—
Kevin L. Unger	3,070	3,070

(1) Amounts reflect the full grant-date fair value of stock awards granted to our non-employee directors during 2015 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of these awards in Note 9 to our consolidated financial statements included elsewhere in this prospectus. There can be no assurance that unvested awards will vest (and, absent vesting, no value will be realized by the executive for the award).

(2) Stock awards payable to Mr. Pelizzon for his service on our board of directors are paid directly to Squadron.

In connection with this offering, we intend to adopt and ask our stockholders to approve the initial terms of a non-employee director compensation policy that consists of a combination of annual retainer fees and long-term equity based compensation. The terms of the non-employee director compensation policy, as it is currently contemplated, are summarized below. Our board of directors is still in the process of considering the non-employee director compensation policy and, accordingly, this summary is subject to change.

We expect each non-employee director will receive an annual cash retainer for his or her services in an amount equal to \$ and additional amounts that have not yet been determined for service on board committees. We further expect that non-employee directors will also receive initial equity awards of , vesting over years, upon election to our board of directors, and thereafter annual grants of on the date of each annual meeting of stockholders, vesting over years, subject to continued service through the applicable vesting date. All stock awards granted to our non-employee directors will vest in full upon the occurrence of a change in control transaction.

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a description of transactions since January 1, 2013 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under “Executive and Director Compensation.”

### **Squadron**

#### *Loan Agreement*

In May 2014, we entered into a second amended and restated loan agreement, or the Loan Agreement, with Squadron, a beneficial owner of more than 5% of our capital stock. Mr. Pelizzon, a director of our company, is the President and Chief Executive Officer of Squadron. The Loan Agreement was further amended on November 19, 2015 to add a \$7.0 million revolving credit facility. Pursuant to the Loan Agreement, Squadron has provided us with (i) a term loan credit facility in a principal amount of \$11.4 million and (ii) a revolving credit facility in a maximum principal amount at any time outstanding of up to \$7.0 million. As of December 31, 2015, we had \$11.4 million in outstanding debt under the term loan credit facility and no outstanding debt under the revolving credit facility. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Indebtedness — Loan Agreement.”

#### *Stockholders Agreement*

On May 27, 2014, we entered into an amended and restated certificate of designations, preferences and rights of preferred stock, or the Preferred Stock Terms. The Preferred Stock Terms provide holders of our Series A Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect one member of our board of directors, and provide holders of our Series B Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect two members of our board of directors, as described in “Management — Board Composition and Election of Directors — Board Composition.”

We expect to amend the Preferred Stock Terms prior to the completion of this offering and for the Preferred Stock Terms to terminate concurrently with the conversion of all shares of our Series A Preferred Stock and Series B Preferred Stock into shares of our common stock immediately prior to the completion of this offering. Prior to this offering, we expect to enter into a stockholders agreement, or the Stockholders Agreement, which will provide current holders of our Series A Preferred Stock and Series B Preferred Stock with certain board representation rights following the completion of this offering.

#### *Supply Relationships*

We currently use FMI Hansa Medical Products, LLC and Structure Medical, LLC as two of our suppliers for components of our products. Each of these entities is affiliated with Squadron. In addition, Mr. Pelizzon, a director of our company, is an equity holder in each of these entities. We do not have long-term contracts with either supplier. For the years ended December 31, 2013, 2014 and 2015, we made payments to FMI Hansa Medical Products, LLC totaling \$870,000, \$1.4 million and \$320,000, respectively. For the years ended December 31, 2013, 2014 and 2015, we made payments to Structure Medical, LLC totaling \$3.5 million, \$2.2 million and \$880,000, respectively.

#### *Real Estate Mortgage*

In connection with the purchase of our office and warehouse space in Warsaw, Indiana in August 2013, we entered into a mortgage note payable to Tawani Enterprises Inc., an affiliate of Squadron. Pursuant to the terms of the mortgage note, we pay Tawani Enterprises Inc. monthly principal and interest installments of \$15,543, with interest compounded at 5% until maturity in August 2028, at which time a final payment of principal and interest is due. The mortgage is secured by the related real estate and building. As of December 31, 2014 and 2015, the mortgage balance was \$1.8 million and \$1.7 million, respectively.

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### *Registration Rights Agreement*

On May 30, 2014, we entered into a registration rights agreement with Squadron, or the Registration Rights Agreement, which provides certain rights relating to the registration under the Securities Act of the shares of common stock issuable to Squadron upon the conversion of its Class A Preferred Stock and Class B Preferred Stock. These registration rights terminate when the securities subject to such rights have been sold pursuant to an effective registration under the Securities Act or pursuant to Rule 144 under the Securities Act. These rights are subject to the 180-day lock-up agreements described in the “Shares Eligible for Future Sale — Lock-Up Agreements” section of this prospectus. See “Description of Capital Stock — Registration Rights” for additional information.

### **Indemnification of Officers and Directors**

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the completion of this offering, will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the DGCL. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see “Management — Limitations of Liability and Indemnification Matters.”

### **Other Transactions**

Mr. Gerritzen is Of Counsel at Bingham Greenbaum Doll LLP, which serves as our legal counsel in connection with various matters. For the years ended December 31, 2013, 2014 and 2015, we paid Bingham Greenbaum Doll LLP \$212,000, \$332,000 and \$173,000, respectively, in legal fees. Mr. Gerritzen does not have a direct interest in the payment of such fees, but has an indirect interest as an employee of the law firm. Mr. Gerritzen spends substantially all of his time working for our company.

### **Related Person Transaction Policy**

Our board of directors has adopted a written related person transaction policy, to be effective upon the completion of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

## PRINCIPAL STOCKHOLDERS

The following table and accompanying footnotes set forth information with respect to the beneficial ownership of our common stock. The following information is based upon shares of common stock outstanding as of December 31, 2015 (after giving effect to the conversion of all shares of our Series A Preferred Stock and our Series B Preferred Stock into shares of common stock, which will occur immediately prior to the completion of this offering) and shares of common stock outstanding following this offering (assuming no exercise of the underwriters' option to purchase additional shares) by:

- each person known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined under the SEC rules and regulations and generally includes voting or investment power over securities. Except in cases where community property laws apply or as indicated in the footnotes to this table, we believe each stockholder identified in the table possesses sole voting and investment power over all shares of equity securities shown as beneficially owned by the stockholder. Shares of common stock subject to options that are currently exercisable or exercisable within 60 days of the date of this prospectus are considered outstanding and beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise indicated, the address of each beneficial owner listed below is c/o OrthoPediatrics Corp., 2850 Frontier Drive, Warsaw, IN 46582.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering	Percentage of Common Stock Beneficially Owned	
		Prior to Offering	After Offering
<b>5% or Greater Stockholders:</b>			
Squadron Capital, LLC <sup>(1)</sup>			
<b>Named Executive Officers and Directors:</b>			
Mark C. Throdahl <sup>(2)</sup>	267,828		
Fred L. Hite	50,000		
David R. Bailey <sup>(3)</sup>	218,674		
Gregory A. Odle <sup>(4)</sup>	217,357		
Terry Schlotterback <sup>(5)</sup>	30,330		
Bernie B. Berry, III <sup>(6)</sup>	65,917		
Bryan W. Hughes <sup>(7)</sup>	1,600		
Marie C. Infante	—		
Alan Kozlowski	—		
Oscar Morales <sup>(8)</sup>	87,524		
Peter J. Munson <sup>(9)</sup>	4,100		
David R. Pelizzon <sup>(10)</sup>			
Kevin L. Unger <sup>(11)</sup>	1,600		
All executive officers and directors as a group (15 persons) <sup>(12)</sup>			

\* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) Includes shares of common stock which Squadron has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015. The address of Squadron is 18 Hartford Ave., PO Box 223, Granby, CT 06035.

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- (2) Includes 2,800 shares of common stock which Mr. Throdahl has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015.
- (3) Includes 32,960 shares of common stock which Mr. Bailey has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015 and 1,200 shares of common stock held by Mr. Bailey in an individual retirement account.
- (4) Includes 85,760 shares of common stock which Mr. Odle has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015 and 4,800 shares of common stock held jointly by Mr. Odle and his spouse.
- (5) Includes 12,196 shares of common stock which Mr. Schlotterback has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015.
- (6) Includes 9,408 shares of common stock which Mr. Berry has the right to acquire pursuant to outstanding warrants and stock options which are or will be immediately exercisable within 60 days of December 31, 2015.
- (7) Includes 1,000 shares of common stock which Mr. Hughes has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015.
- (8) Includes 4,000 shares of common stock which Mr. Moralez has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015. Also includes 74,296 shares of common stock owned by VisionTech Partners, LLC (formerly known as Stepstone Business Partners, LLC), and 6,828 shares of common stock which VisionTech has the right to acquire pursuant to outstanding warrants which are or will be immediately exercisable within 60 days of December 31, 2015. As the manager of VisionTech, Mr. Moralez has the power to direct the disposition of such shares.
- (9) Includes 1,000 shares of common stock which Mr. Munson has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015 and 2,500 shares of common stock held by Mr. Munson in an individual retirement account.
- (10) Consists of        shares of common stock owned by Squadron and        shares of common stock which Squadron has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015. As the President and Chief Executive Officer of Squadron, Mr. Pelizzon has the power to direct the voting and disposition of such shares.
- (11) Includes 1,000 shares of common stock which Mr. Unger has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015.
- (12) Includes shares of common stock issuable upon the exercise of outstanding warrants and stock options which are or will be immediately exercisable within 60 days of December 31, 2015, as set forth in previous footnotes. Also includes 28,632 shares of common stock and 14,216 shares of common stock which Dr. Armstrong and Mr. Gerritzen, respectively, has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2015 and 1,018 shares of common stock held jointly by Dr. Armstrong and his spouse.

## DESCRIPTION OF CAPITAL STOCK

### General

Following the completion of this offering, our authorized capital stock will consist of      shares of common stock, par value \$0.00025 per share, and      shares of preferred stock, par value \$0.00025 per share. The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering, our outstanding warrants, the investors' rights agreement and of the DGCL. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, warrants and investors' rights agreement, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which the prospectus is a part, as well as the relevant provisions of the DGCL.

### Common Stock

As of December 31, 2015, we had 3,489,567 shares of common stock outstanding, which were owned by 357 stockholders.

Holders of our common stock are entitled to one vote for each share held of record on all matters on which stockholders are entitled to vote generally, including the election or removal of directors. The holders of our common stock do not have cumulative voting rights in the election of directors.

Upon our liquidation, dissolution or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of our common stock will be entitled to receive pro rata our remaining assets available for distribution. Holders of our common stock do not have preemptive, subscription, redemption or conversion rights. The common stock will not be subject to further calls or assessment by us. There will be no redemption or sinking fund provisions applicable to the common stock. All shares of our common stock that will be outstanding at the time of the completion of the offering will be fully paid and non-assessable. The rights, powers, preferences and privileges of holders of our common stock will be subject to those of the holders of any shares of our preferred stock we may authorize and issue in the future.

### Preferred Stock

On May 27, 2014, we entered into the Preferred Stock Terms, which provide holders of our Series A Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect one member of our board of directors, and provide holders of our Series B Preferred Stock and shares of our common stock issued upon the conversion thereof with the right, exclusively and as a separate class, to elect two members of our board of directors. Pursuant to the Preferred Stock Terms, shares of our Series A Preferred Stock and Series B Preferred Stock accrue dividends at the rate of eight percent per annum of their original issue price, compounded quarterly. The Preferred Stock Terms provide holders with customary redemption and optional conversion rights and provide for mandatory conversion into shares of our common stock upon certain events, including a qualified initial public offering. Upon a conversion or redemption, all accrued, unpaid dividends are payable. We expect to amend the Preferred Stock Terms prior to the completion of this offering and for the Preferred Stock Terms to terminate concurrently with the conversion of all shares of our Series A Preferred Stock and Series B Preferred Stock into shares of our common stock immediately prior to the completion of this offering.

Upon completion of this offering, all of our previously outstanding shares of Series A Preferred Stock and Series B Preferred Stock will have been converted into common stock. Under the terms of our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to      shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations



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or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Options**

As of December 31, 2015, options to purchase 371,449 shares of our common stock at a weighted-average exercise price of \$15.96 were outstanding under the 2007 Plan, all of which were vested and exercisable as of that date.

### **Warrants**

As of December 31, 2015, warrants to purchase 65,823 shares of our common stock at a weighted-average exercise price of \$18.11 per share were outstanding. These warrants will expire between September 2018 and December 2020.

### **Dividends**

The DGCL permits a corporation to declare and pay dividends out of “surplus” or, if there is no “surplus,” out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. “Surplus” is defined as the excess of the net assets of the corporation over the amount determined to be the capital of the corporation by the Board of Directors. The capital of the corporation is typically calculated to be (and cannot be less than) the aggregate par value of all issued shares of capital stock. Net assets equal the fair value of the total assets minus total liabilities. The DGCL also provides that dividends may not be paid out of net profits if, after the payment of the dividend, remaining capital would be less than the capital represented by the outstanding stock of all classes having a preference upon the distribution of assets.

Declaration and payment of any dividend will be subject to the discretion of our board of directors. The time and amount of dividends will be dependent upon our financial condition, operations, cash requirements and availability, debt repayment obligations, capital expenditure needs, restrictions in our debt instruments, industry trends, the provisions of Delaware law affecting the payment of distributions to stockholders and any other factors our board of directors may consider relevant.

At the present time, we have no plans to declare or pay any dividends in the near future and intend to retain all of our future earnings, if any, generated by our operations for the development and growth of our business. In addition, the terms of any future credit agreements may limit our ability to pay dividends.

### **Annual Stockholder Meetings**

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that annual stockholder meetings will be held at a date, time and place, if any, as exclusively selected by our board of directors. To the extent permitted under applicable law, we may conduct meetings by remote communications, including by webcast.

### **Registration Rights**

Pursuant to the Registration Rights Agreement, Squadron (together with any Permitted Transferee, as defined in the Registration Rights Agreement) will be entitled to the following rights with respect to the registration under the Securities Act of the shares of common stock issuable to Squadron upon the conversion of its Class A Preferred Stock and Class B Preferred Stock immediately prior to the completion of this offering. The registration of shares of common stock as a result of the following rights

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being exercised would enable Squadron to trade such shares without restriction under the Securities Act when the applicable registration statement is declared effective. These rights are subject to the 180-day lock-up agreements described in the “Shares Eligible for Future Sale — Lock-Up Agreements” section of this prospectus.

### *Demand Registration Rights*

At any time after the effective date of the registration statement of which this prospectus forms a part, if Squadron requests in writing that we file a registration statement on Form S-1, then we may be required to register its shares. We are obligated to effect at most two registrations in response to these demand registration rights. If Squadron intends to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

### *Piggyback Registration Rights*

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, Squadron will be entitled to notice of the registration and to include its shares of registrable securities in the registration. If our proposed registration involves an underwriting, we, in consultation with the managing underwriter of such offering, will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

### *Form S-3 Registration Rights*

If at any time after we become eligible under the Securities Act to register our shares on Form S-3, if Squadron requests in writing that we register its shares for public resale on Form S-3, we will be required to effect such registration, subject to specified exceptions, conditions and limitations, including that the shares to be registered have an anticipated net aggregate offering price of at least \$5 million.

### *Expenses*

Ordinarily, other than stock transfer taxes and all discounts, commissions or other amounts payable to underwriters or brokers, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all qualification fees, printers’ and accounting fees, fees and disbursements of our counsel, blue sky fees and expenses and the reasonable fees and disbursements of a counsel for the selling holders of registrable securities.

### *Termination of Registration Rights*

The registration rights terminate when the securities subject to such rights have been sold pursuant to an effective registration under the Securities Act or pursuant to Rule 144 under the Securities Act.

## **Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law**

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### *Undesignated Preferred Stock*

The ability of our board of directors, without action by the stockholders, to issue up to        shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of

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directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

### *Stockholder Meetings*

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

### *Requirements for Advance Notification of Stockholder Nominations and Proposals*

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

### *Elimination of Stockholder Action by Written Consent*

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

### *Staggered Board*

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see “Management — Board Composition and Election of Directors.” This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

### *Removal of Directors*

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

### *Stockholders Not Entitled to Cumulative Voting*

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

### *Delaware Anti-Takeover Statute*

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

### *Choice of Forum*

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action

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asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws; (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our amended and restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise. This choice of forum provision has important consequences to our stockholders. See “Risk Factors — Risks Related to this Offering and Ownership of Our Common Stock — Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.”

### *Amendment of Charter Provisions*

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two-thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be .

### **NASDAQ Listing**

We intend to apply to have our common stock approved for listing on The NASDAQ Global Market under the symbol “KIDS.”

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has not been a public market for our common stock. We cannot predict what effect, if any, future sales of shares of common stock, or the availability for future sales of shares of common stock will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of common stock, including shares issued upon the exercise of outstanding options, in the public market or the perception that such sales could occur, could materially and adversely affect the market price of our common stock and could impair our future ability to raise capital through the sale of our equity or equity-related securities at a time and price that we deem appropriate.

Upon the completion of this offering, we will have      shares of common stock outstanding. All shares sold in this offering will be freely tradable without registration under the Securities Act and without restriction by persons other than our “affiliates” (as defined in Rule 144 under the Securities Act, or Rule 144). The      shares of common stock held by Squadron and certain of our directors, officers and employees after this offering, based on the number of shares outstanding as of December 31, 2015, will be “restricted” securities under the meaning of Rule 144 and may not be sold in the absence of registration under the Securities Act, unless an exemption from registration is available, including the exemptions pursuant to Rule 144.

The restricted shares held by our affiliates will be available for sale in the public market at various times after the date of this prospectus pursuant to Rule 144 following the expiration of the applicable lock-up period.

### Lock-Up Agreements

We and each of our directors, executive officers and significant equity holders have agreed that we and they will not, subject to limited exceptions that are described in more detail in the section in this prospectus entitled “Underwriting,” during the period ending 180 days after the date of this prospectus:

- offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exchangeable or exercisable for, shares of our common stock;
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our securities, whether settled by delivery of shares of our common stock or such other securities, in cash or otherwise;
- make any demand for or exercise any right with respect to, the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock; or
- publicly disclose the intention to do any of the foregoing.

Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the restricted period.

Upon the expiration of the lock-up period, all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### Rule 144

#### *Affiliate Resales of Restricted Securities*

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months

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would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately      shares immediately after this offering; or
- the average weekly trading volume in our common stock on NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and NASDAQ concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

### **Registration Rights**

Based on the number of shares of our Series A Preferred Stock and Series B Preferred Stock held by Squadron as of December 31, 2015 and assuming the conversion of all such shares of Series A Preferred Stock and Series B Preferred Stock into      shares of our common stock immediately prior to the completion of this offering,      shares of common stock will be entitled to various rights with respect to registration under the Securities Act upon the completion of this offering. Such registration would result in these shares becoming fully tradable without restriction under the Securities Act when the applicable registration statement is declared effective. These rights are subject to the 180-day lock-up agreements described in “— Lock-Up Agreements”. See “Description of Capital Stock — Registration Rights” for additional information.

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO  
NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, the Treasury regulations promulgated thereunder, or the Treasury Regulations, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

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**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### **Definition of a Non-U.S. Holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

### **Distributions**

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will first constitute a return of capital and be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “— Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, backup withholding and payments made to certain foreign accounts, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation may also be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such



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effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Sale or Other Taxable Disposition**

Subject to the discussion below regarding backup withholding and payments made to certain foreign accounts, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation may also be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected earnings and profits for the taxable year that are attributable to such gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. In general, we would be a USRPHC if the fair market value of our USRPIs comprised at least half of the fair market value of our total worldwide interests in real property plus our other business assets. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by the applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Payments of dividends on our common stock to a Non-U.S. Holder will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States

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or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code, the Treasury Regulations and other official guidance (commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, and gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence, reporting and withholding obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence, reporting and withholding requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. The FATCA withholding tax will apply to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from imposition of withholding tax pursuant to an applicable tax treaty with the United States or U.S. domestic law. We will not pay additional amounts to holders of our common stock in respect of amounts withheld.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## UNDERWRITING

Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

Underwriters	Number of Shares
Piper Jaffray & Co.	
Stifel, Nicolaus & Company, Incorporated	
William Blair & Company, L.L.C.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

### Discounts and Commissions

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of this offering may be changed. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public Offering Price	\$	\$	\$
Underwriter Discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discount and commissions, are approximately \$ million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount not to exceed \$ as set forth in the underwriting agreement.

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares, described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased.

### **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less the underwriting discount and commissions. The underwriters may exercise this option solely for the purpose of covering overallocments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the table above bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

### **No Sales of Similar Securities**

We, our executive officers and directors and substantially all of our other stockholders, optionholders and warrantholders have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable or exercisable for, or that represent the right to receive shares of our common stock, for 180 days after the date of the prospectus used to sell our common stock without first obtaining the written consent of Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;
- sell any option or contract to purchase any shares of our common stock;
- purchase any option or contract to sell any shares of our common stock;
- grant any option, right or warrant to purchase any shares of our common stock;
- make any short sale or otherwise transfer or dispose of any shares of our common stock;
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of our common stock, whether any such swap or transaction is to be settled by delivery of shares of our common stock or other securities, in cash or otherwise;
- make any demand for or exercise any right with respect to the registration of our common stock; or
- publicly announce the intention to do any of the foregoing.

The restrictions in the preceding paragraph do not apply to transfers of securities:

- as a bona fide gift or gifts;
- to any trust, partnership, limited liability company or other entity for the direct or indirect benefit of the stockholder or the immediate family of the stockholder;
- if the stockholder is a corporation, partnership, limited liability company, trust or other business entity, (i) transfers to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate of the stockholder or (ii) distributions of our common stock or any security convertible into or exercisable for our common stock to limited partners, limited liability company members or stockholders of the stockholder;
- if the stockholder is a trust, to the beneficiary of such trust;
- by testate succession or intestate succession; or
- pursuant to the underwriting agreement;

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provided, in the case of a transfer described in bullets one through five above, that such transfer does not involve a disposition for value, and each transferee agrees to be subject to the restrictions described in the immediately preceding paragraph and that no filing by any party under Section 16(a) of the Exchange Act shall be required or shall be made voluntarily in connection with such transfer.

In addition, the transfer restrictions described above do not apply to:

- the exercise (including by means of a “net” or “cashless” exercise) of stock options granted pursuant to our equity incentive plans or warrants that are described in this prospectus; provided that the stockholder’s securities received upon exercise shall remain subject to the transfer restrictions;
- transfers to us to satisfy tax withholding obligations pursuant to our equity incentive plans that are described in this prospectus;
- transfers to us by an executive officer upon the death, disability or termination of employment, in each case, of such executive officer;
- transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of our common stock involving a change of control; provided that in the event such tender offer, merger, consolidation or other such transaction is not completed, the shares of our common stock shall remain subject to the transfer restrictions;
- the conversion of the outstanding shares of our preferred stock into shares of our common stock; provided that the shares of our common stock received upon conversion shall remain subject to the transfer restrictions;
- transfers of shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock by operation of law to a spouse, former spouse, domestic partner, former domestic partner, child or other dependent pursuant to a qualified domestic order or in connection with a divorce settlement; provided that the transferee agrees in writing to be bound by the transfer restrictions prior to such transfer and, if the stockholder is required to file a report under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of our common stock for 180 days after the date of this prospectus, such stockholder shall include a statement in such report to the effect that the transfer occurred by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, as applicable; or
- the establishment of any 10b5-1 plan, provided that no sales of the stockholder’s common stock will be made under such plans for 180 days after the date of this prospectus.

## **Listing**

We intend to apply to list our common stock on The NASDAQ Global Market under the symbol “KIDS.” In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representative. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representative believes to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations and the prospects for, and timing of, our future net sales;

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- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after this offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing shares of our common stock. However, the underwriters may engage in transactions that stabilize the price of our common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. “Naked” short sales are sales in excess of the overallotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of our common stock made by the underwriters in the open market prior to the completion of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on NASDAQ, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Electronic Offer, Sale and Distribution of Shares**

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, one or more of the underwriters may facilitate Internet distribution for this offering to certain of their Internet subscription customers. Any such underwriter may allocate a limited number of shares for sale to its online brokerage customers. An

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electronic prospectus is available on the Internet websites maintained by any such underwriter. Other than the prospectus in electronic format, the information on the websites of any such underwriter is not part of this prospectus.

### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **Selling Restrictions**

#### *European Economic Area*

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

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### *United Kingdom*

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the “FSMA”)) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

### *Canada*

The common stock may be sold only to purchasers purchasing as principal that are both “accredited investors” as defined in National Instrument 45-106 Prospectus and Registration Exemptions and “permitted clients” as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

### *Hong Kong*

The common stock may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

### *Singapore*

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries’



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rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

- (i) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- (ii) where no consideration is or will be given for the transfer; or
- (iii) where the transfer is by operation of law.

### *Switzerland*

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the “SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common stock.

### *United Arab Emirates*

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the “UAE”), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority (“DFSA”), a regulatory authority of the Dubai International Financial Centre (“DIFC”). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The common shares may not be offered to the public in the UAE and/or any of the free zones.

The common shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

### *France*

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

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This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the “AMF”) for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;
2. persons or entities referred to in Point 2°, Section II of Article L. 411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and
3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

## **LEGAL MATTERS**

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Latham & Watkins LLP, Chicago, Illinois. Cooley LLP, New York, New York, has acted as counsel for the underwriters in connection with this offering.

## **EXPERTS**

The consolidated financial statements of OrthoPediatics Corp. and subsidiary as of and for the years ended December 31, 2014 and 2015, included in this Prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

Upon completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov). We also maintain a website at [www.orthopediatrics.com](http://www.orthopediatrics.com), at which, following the completion of this offering, you may access our SEC filings free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

OrthoPediatics Corp.  
Warsaw, Indiana

We have audited the accompanying consolidated balance sheets of OrthoPediatics Corp. and subsidiary (the “Company”) as of December 31, 2014 and 2015, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders’ deficit, and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of OrthoPediatics Corp. and subsidiary as of December 31, 2014 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ *DELOITTE & TOUCHE LLP*

Indianapolis, Indiana  
March 14, 2016

**ORTHOPEDIATRICS CORP.**

**CONSOLIDATED BALANCE SHEETS**

**December 31, 2014 and 2015**

*(in thousands, except share and per share information)*

	2014	2015	Pro Forma Stockholders' Equity (unaudited)
<b>ASSETS</b>			
Current assets:			
Cash	\$ 6,581	\$ 3,878	
Accounts receivable – trade, less allowance for doubtful accounts of \$0 and \$120, respectively	2,771	3,818	
Inventories, net	12,837	11,708	
Inventories held by international distributors, net	4,491	2,842	
Prepaid expenses and other current assets	252	222	
Assets held for sale	577	—	
Total current assets	27,509	22,468	
Property and equipment, net	7,467	7,336	
Other assets:			
Amortizable intangible assets, net	592	627	
Other intangible assets	260	260	
Total other assets	852	887	
Total assets	<u>\$ 35,828</u>	<u>\$ 30,691</u>	
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>			
Current liabilities:			
Accounts payable – trade	\$ 645	\$ 1,999	
Accrued compensation and benefits	1,484	2,257	
Current portion of long-term debt with affiliate	97	101	
Current portion of research and development fee obligation	566	1,517	
Other current liabilities	426	463	
Total current liabilities	3,218	6,337	
Long-term liabilities:			
Long-term debt with affiliate, net of current portion	13,141	13,039	—
Research and development fee obligation, net of current portion	1,492	—	—
Total long-term liabilities	14,633	13,039	—
Total liabilities	17,851	19,376	—
Commitments and contingencies (Note 16)			
Redeemable convertible preferred stock:			
Series A preferred stock, \$0.00025 par value; \$4,005 cumulative preferred dividends, December 31, 2014, \$5,654, December 31, 2015; 1,000,000 shares authorized, issued and outstanding	20,005	21,654	—
Series B preferred stock, \$0.00025 par value; \$1,731 cumulative preferred dividends, December 31, 2014, \$4,879 December 31, 2015; 6,000,000 shares authorized; 4,446,978 shares issued and outstanding	40,625	43,773	—
Stockholders' deficit:			
Common stock, \$0.00025 par value; 12,000,000 shares authorized, December 31, 2015, 2,992,846 shares and 3,489,567 shares issued and outstanding as of December 31, 2014 and 2015	1	1	—
Additional paid-in capital	21,017	17,449	—
Accumulated deficit	(63,671)	(71,562)	—
Total stockholders' deficit	(42,653)	(54,112)	—
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 35,828</u>	<u>\$ 30,691</u>	<u>\$ —</u>

See notes to consolidated financial statements.

**ORTHOPEDIATRICS CORP.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years Ended December 31, 2014 and 2015**

*(in thousands, except share and per share information)*

	2014	2015
Net revenue	\$ 23,684	\$ 31,004
Cost of revenue	7,085	9,367
Gross profit	16,599	21,637
Operating expenses:		
Sales and marketing	12,185	15,033
General and administrative	9,875	11,407
Research and development	1,683	1,789
Total operating expenses	23,743	28,229
Operating loss	(7,144)	(6,592)
Other expenses:		
Interest expense	2,549	1,230
Other expense	67	31
Total other expenses	2,616	1,261
Net loss from continuing operations	(9,760)	(7,853)
(Gain) loss from discontinued operations	(211)	38
Net loss	\$ (9,549)	\$ (7,891)
Net loss attributable to common stockholders	\$ (12,804)	\$ (12,688)
Weighted average common shares – basic and diluted	2,603,425	2,603,517
Net loss per share attributable to common stockholders – basic and diluted	\$ (4.92)	\$ (4.87)
Pro forma weighted average common shares – basic and diluted (unaudited)		
Pro forma net loss per share attributable to common stockholders – basic and diluted (unaudited)	\$ —	\$ —

See notes to consolidated financial statements.

ORTHOPEDIATRICS CORP.

**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK  
AND STOCKHOLDERS' DEFICIT**

**Years Ended December 31, 2014 and 2015**  
*(in thousands, except share information)*

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Value	Shares	Value	Shares	Value			
Balance at January 1, 2014	1,000,000	\$ 18,481	—	\$ —	2,883,492	\$ 1	\$ 23,566	\$ (54,122)	\$ (30,555)
Net loss	—	—	—	—	—	—	—	(9,549)	(9,549)
Issuance of preferred stock, net of issuance cost	—	—	1,928,962	16,864	—	—	—	—	—
Conversion of debt to preferred stock	—	—	2,518,016	22,030	—	—	—	—	—
Stock options	—	—	—	—	4,800	—	26	—	26
Accretion of redeemable preferred stock to redemption value	—	1,524	—	1,731	—	—	(3,255)	—	(3,255)
Restricted stock	—	—	—	—	104,554	—	680	—	680
Balance at December 31, 2014	1,000,000	20,005	4,446,978	40,625	2,992,846	1	21,017	(63,671)	(42,653)
Net loss	—	—	—	—	—	—	—	(7,891)	(7,891)
Accretion of redeemable preferred stock to redemption value	—	1,649	—	3,148	—	—	(4,797)	—	(4,797)
Restricted stock	—	—	—	—	496,721	—	1,229	—	1,229
Balance at December 31, 2015	1,000,000	\$ 21,654	4,446,978	\$ 43,773	3,489,567	\$ 1	\$ 17,449	\$ (71,562)	\$ (54,112)

See notes to consolidated financial statements.



**ORTHOPEDIATRICS CORP.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Years Ended December 31, 2014 and 2015**

*(in thousands)*

	<u>2014</u>	<u>2015</u>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (9,549)	\$ (7,891)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on sale of assets held for sale	—	38
Depreciation and amortization	1,577	1,854
Stock-based compensation	706	1,229
Changes in certain current assets and liabilities:		
Accounts receivable – trade	375	(1,047)
Inventories	(360)	1,623
Inventories held by international distributors	(2,318)	1,649
Prepaid expenses and other current assets	59	30
Accounts payable – trade	(445)	1,354
Accrued expenses and other liabilities	379	810
Research and development fee obligation	(346)	(541)
Net cash used in operating activities	<u>(9,922)</u>	<u>(892)</u>
<b>INVESTING ACTIVITIES</b>		
Proceeds from assets held for sale	42	539
Purchases of licenses	(176)	(41)
Purchases of property and equipment	(3,142)	(2,211)
Net cash used in investing activities	<u>(3,276)</u>	<u>(1,713)</u>
<b>FINANCING ACTIVITIES</b>		
Payments on convertible term notes	(520)	—
Payments on promissory payable to affiliate	(538)	—
Proceeds from issuance of debt with affiliate	4,000	—
Proceeds from issuance of preferred stock	16,864	—
Payments on mortgage notes	(85)	(98)
Net cash (used in) provided by financing activities	<u>19,721</u>	<u>(98)</u>
NET (DECREASE) INCREASE IN CASH	6,523	(2,703)
Cash, beginning of year	58	6,581
Cash, end of year	<u>\$ 6,581</u>	<u>\$ 3,878</u>
<b>SUPPLEMENTAL DISCLOSURES</b>		
Cash paid for interest	\$ 2,549	\$ 1,230
Issuance of preferred stock for conversion of promissary note	\$ 22,030	\$ —
Issuance of preferred stock for conversion of accrued interest	\$ 510	\$ —
Accretion of redeemable convertible preferred stock	\$ 3,255	\$ 4,797
Transfer of instruments from property and equipment to inventory	\$ 976	\$ 474

See notes to consolidated financial statements.

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

*(in thousands, except share information)*

**NOTE 1 — BUSINESS**

OrthoPediatrics Corp. is a medical device company committed to designing, developing and marketing anatomically appropriate implants and devices for children with orthopedic conditions, giving pediatric orthopedic surgeons and caregivers the ability to treat children with technologies specifically designed to meet their needs. Initially organized as an Indiana limited liability company on August 31, 2006, OrthoPediatrics Corp. was converted to a Delaware corporation on November 30, 2007. OrthoPediatrics Corp. sells its specialized products, including PediLoc, PediPlates, Cannulated Screws, PediFlex nail, PediNail, PediLoc Tibia, ACL Reconstruction System, Locking Cannulated Blade, Locking Proximal Femur, Spica Tables and RESPONSE Spine, to various hospitals and medical facilities throughout the United States and various international markets. We currently use a contract manufacturing model for the manufacturing of implants and related surgical instrumentation.

Our controlling investor is Squadron Capital, LLC (“Squadron”), a private equity firm headquartered near Hartford, Connecticut.

**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

We have prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”). The accompanying consolidated financial statements include the accounts of OrthoPediatrics Corp. and its wholly-owned subsidiary, OrthoPediatrics United States Distribution Corp. (collectively, the “company,” or “we,” “our” or “us”). All intercompany balances and transactions have been eliminated from the consolidated financial statements.

The accompanying consolidated financial statements have been prepared assuming our company will continue as a going concern. We have experienced recurring losses from operations since our inception, and have an accumulated deficit of \$71,562 at December 31, 2015. Our note payable and revolving credit facility with Squadron matures and our redeemable convertible preferred stock becomes redeemable in May 2017. We are dependent upon further or continued financing by investors to accommodate these potential future obligations. Management continues to monitor cash flows and liquidity on a regular basis. We believe that our cash balance at December 31, 2015, expected cash flows from operations and the \$7,000 availability under the revolving credit facility are sufficient to enable us to maintain current and essential planned operations for the next year. Our ability to fund planned operations internally beyond that date may be substantially dependent upon our ability to obtain sufficient funding at terms acceptable to us.

***Unaudited Pro Forma Stockholders’ Equity***

***Use of Estimates***

Preparation of our consolidated financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses, as of the date of the consolidated financial statements. By their nature, these judgments are subject to an inherent degree of uncertainty. We use historical experience and other assumptions as the basis for our judgment and estimates. Because future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Any changes in those estimates will be reflected in our consolidated financial statements.

***Foreign Currency Transactions***

We currently bill our international distributors in U.S. dollars, resulting in minimal foreign exchange transaction expense. The impact of foreign currency transaction expense is immaterial to our financial results.

ORTHOPEDIATRICS CORP.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2014 and 2015

(in thousands, except share information)

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

*Fair Value of Financial Instruments*

The accounting standards related to fair value measurements define fair value and provide a consistent framework for measuring fair value under the authoritative literature. Valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions. This guidance only applies when other standards require or permit the fair value measurement of assets and liabilities. The guidance does not expand the use of fair value measurements. A fair value hierarchy was established, which prioritizes the inputs used in measuring fair value into three broad levels:

Level 1 — Quoted prices in active markets for identical assets or liabilities;

Level 2 — Observable market-based inputs or unobservable inputs that are corroborated by market data; and

Level 3 — Significant unobservable inputs that are not corroborated by market data. Generally, these fair value measures are model-based valuation techniques such as discounted cash flows, and are based on the best information available, including our own data.

We do not have any assets or liabilities that are measured on a recurring basis under the presented fair value hierarchy.

*Revenue Recognition — United States*

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists, usage or shipment has occurred, the price to the buyer is fixed or determinable and collectability is reasonably assured.

Revenue in the United States is generated primarily from the sale of our implants, and to a much lesser extent from the sale of our instruments. Sales in the United States are primarily to hospital accounts through independent sales agencies. The products are primarily consigned to our independent sales agencies or the hospitals, and revenue is recognized when the products are used by or shipped to the hospital for surgeries on a case by case basis. On rare occasions, hospitals purchase products for their own inventory, and revenue is recognized when the products are shipped and the title and risk of loss passes to the hospital customer. Pricing for each customer is dictated by a unique pricing agreement which does not generally include rebates or discounts.

*Revenue Recognition — International*

Outside of the United States, we sell our products through independent stocking distributors. Generally, the distributors are allowed to return product, and some are thinly capitalized. Based on our history of collections and returns from international customers, we have concluded that collectability is not reasonably assured at the time of delivery. Accordingly, we do not recognize international revenue and associated costs of revenue at the time title transfers, but rather when cash has been received. Until such payment, the cost of revenue is recorded as inventories held by international distributors, net of adjustment for estimated unreturnable inventory, on the balance sheets.

At December 31, 2014 and 2015, we have invoiced international sales to distributors that have not been recognized as revenue totaling \$7,353 and \$5,190, respectively. Associated costs of revenue, which is reported as inventory held by distributors was \$4,491 and \$2,842 at December 31, 2014 and 2015, respectively.

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

*(in thousands, except share information)*

**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)**

***Cash and Cash Equivalents***

We maintain cash in bank deposit accounts which, at times, may exceed federally insured limits. To date, we have not experienced any loss in such accounts. We consider all highly liquid investments with original maturity of three months or less to be cash equivalents. The carrying amounts reported in the balance sheet for cash are valued at cost, which approximates fair value.

***Accounts Receivable — United States***

Domestic accounts receivables are uncollateralized customer obligations due under normal trade terms, generally requiring payment within 30 days from the invoice date. Account balances with invoices over 30 days past due are considered delinquent. No interest is charged on past due accounts. Payments of accounts receivable are applied to the specific invoices identified on the customer's remittance advice or, if unspecified, to the customer's account as an unapplied credit.

The carrying amount of domestic accounts receivable is reduced by an allowance that reflects management's best estimate of the amounts that will not be collected, determined principally on the basis of historical experience, management's assessment of the collectability of specific customer accounts and the aging of the accounts receivable. All accounts or portions thereof deemed to be uncollectible or to require an excessive collection cost are written off to the allowance for doubtful accounts.

***Inventories***

Inventories are stated at the lower of cost or market, with cost determined using the first-in-first-out method. Inventories, which consist of implants and instruments held in our warehouse or with third-party distributors, are considered finished goods and are purchased from third parties.

We evaluate the carrying value of our inventories in relation to the estimated forecast of product demand, which takes into consideration the life cycle of the product. A significant decrease in demand could result in an increase in the amount of excess inventory on hand, which could lead to additional reserves for excess and obsolete inventory.

The need to maintain substantial levels of inventory impacts our estimates for excess and obsolete inventory. Each of our implant systems are designed to include implantable products that come in different sizes and shapes to accommodate the surgeon's needs. Typically, a small number of the set components are used in each surgical procedure. Certain components within each set may become obsolete before other components based on the usage patterns. We adjust inventory values, as needed, to reflect these usage patterns and life cycle.

In addition, we continue to introduce new products, which we believe will increase our revenue and relationships with surgeons. As a result, we may be required to take additional charges for excess and obsolete inventory in the future.

Charges for excess and obsolete inventory are included in the cost of revenue and were \$873 and \$341, for 2014 and 2015, respectively.

***Property and Equipment, net***

Property and equipment are carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of the assets. When assets are retired or otherwise disposed of, costs and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in operations for the period. Maintenance and repairs that prolong or extend the useful life are capitalized, whereas standard maintenance, replacements, and repair costs are expensed as incurred.

**ORTHOPEDIATRICS CORP.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****For the years ended December 31, 2014 and 2015***(in thousands, except share information)***NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)**

Instruments are hand-held devices, specifically designed for use with our implants and are used by surgeons during surgery. Instruments deployed within the United States are carried at cost less accumulated depreciation and are recorded in property and equipment, net on the balance sheets.

Sample inventory consists of our implants and instruments, and are maintained to market and promote our products. Sample inventory is carried at cost less accumulated depreciation.

Depreciable lives are generally as follows:

Building and building improvements	25 to 30 years
Furniture and fixtures	5 to 7 years
Computer equipment	3 to 5 years
Business software	3 years
Office and other equipment	5 to 7 years
Instruments	5 years
Sample inventory	2 years

***Amortizable Intangible Assets, net***

Amortizable intangible assets include fees necessary to secure various patents and licenses. Amortization is calculated on a straight-line basis over the estimated useful life of the patents and licenses. Amortization commences at the time of patent approval, and for licenses upon market launch. Intangible assets are amortized over a 10 to 16 year period.

Amortizable intangible assets are assessed for impairment annually or whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to future net undiscounted cash flows expected to be generated by the associated asset. If such assets are determined to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair market value of the assets. No impairment charges were recorded in 2014 or 2015.

***Other Intangible Assets***

We have indefinitely-lived tradename assets, which are reviewed for impairment by performing a quantitative analysis, annually in the fourth quarter or whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to future net undiscounted cash flows expected to be generated by the associated asset. If such assets are determined to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair market value of the assets. No impairment charges were recorded in 2014 or 2015.

***Shipping and Handling Costs***

Shipping and handling costs that are billed to the customer are included in net revenue and amounted to \$271 and \$279, in 2014 and 2015, respectively. Shipping and handling costs that are not billed to the customer are included in sales and marketing expenses and amounted to \$967 and \$1,454, in 2014 and 2015, respectively.

***Cost of Revenue***

Cost of revenue consists primarily of products purchased from third-party suppliers, excess and obsolete inventory adjustments, inbound freight, and royalties. Our implants and instruments are manufactured to our specifications by third-party suppliers who meet our manufacturer qualifications standards. Our

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

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**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)**

third-party manufacturers are required to meet Food and Drug Administration (“FDA”), International Organization for Standardization and other country specific quality standards. The majority of our implants and instruments are produced in the United States.

***Sales and Marketing Expenses***

Sales and marketing expenses primarily consist of commissions to our domestic independent sales agencies and consignment distributors, as well as compensation, commissions, benefits and other related costs for personnel we employ. Commissions and bonuses are generally based on a percentage of sales. Our international independent distributors purchase instrument sets and replenishment stock for resale, and we do not pay commissions or any other sales related costs for international sales.

***Advertising Costs***

Advertising costs consist primarily of print advertising, trade shows, and other related expenses. Advertising costs are expensed as incurred and amounted to \$877 and \$826 in 2014 and 2015, respectively, and are recorded as a component of sales and marketing expense.

***Research and Development Costs***

Research and development costs are expensed as incurred. Our research and development expenses primarily consist of costs associated with engineering, product development, consulting services, outside prototyping services, outside research activities, materials, development and protection of our intellectual property portfolio and other costs associated with development of our products. We also include related personnel and consultants’ compensation expense.

Research and development costs were \$1,683 and \$1,789 in 2014 and 2015, respectively.

At December 31, 2014 and 2015, we also had a research and development fee obligation to a third-party for their assistance in the development of our first generation spine system and our locking cannulated blade and locking proximal femur hip systems. This fee obligation totaled \$2,058 and \$1,517, respectively.

***Stock-Based Compensation***

We maintain an Amended and Restated 2007 Equity Incentive Plan (the “Plan”) that provides for grants of options and restricted stock to employees, Board members and associated third-party representatives of our company as determined by the Board of Directors. This Plan has authorized 1,585,000 shares for award.

Options holders, upon vesting, may purchase common stock at the exercise price, which is the estimated fair value of our common stock on the date of grant. Option grants generally vest immediately or over a three year period. No stock options were granted in 2014 or 2015.

Restricted stock may not be transferred prior to the expiration of the restricted period. The restricted stock that has been granted has restriction periods that generally last until the earlier of six years from the date of grant, or an Initial Public Offering (“IPO”) or change in control, as defined in the Plan.

We estimate the fair value of stock options and restricted stock at the grant date. Stock-based compensation is recognized ratably over the requisite service period, which is generally the vesting period for stock options and the restriction period for restricted stock.

Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock options. Use of the valuation methodology

**ORTHOPEDIATRICS CORP.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****For the years ended December 31, 2014 and 2015****(in thousands, except share information)****NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)**

requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, and the risk free rate of return for a period that approximates the expected term of our stock options. Because we have been a privately-held company with a limited operating history, we utilize the historical stock price volatility from a representative group of comparable industry competitors to estimate expected stock price volatility.

In determining the fair value of our common stock at the grant date, which is the basis for the fair value of stock based awards, we use the market approach, which is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. In using the market approach, we consider both the guideline public company method and the precedent transaction method. Given the absence of a public trading market for our common stock, we exercise reasonable judgment and consider a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including: the preferences and dividends of our redeemable convertible preferred stock relative to those of our common stock; our operating results and financial conditions, including our level of available capital resources; equity market conditions affecting comparable public companies; and general U.S. market conditions and the lack of marketability of our common stock. For restricted stock awards, we apply a discount for lack of marketability to the fair value of common shares due to estimate the impact of valuing a minority interest in our company as a closely held, non-public company with no liquid market for its shares.

***Redeemable Convertible Preferred Stock***

We classify redeemable convertible preferred stock that is redeemable at the option of the holder outside of permanent equity. The carrying value of the redeemable convertible preferred stock is increased by periodic accretion to its redemption value to reflect accumulated dividends. In the absence of retained earnings, these accretion charges are recorded against additional paid-in capital, if any, and then to accumulated deficit.

***Income Taxes***

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the valuation allowance.

We record uncertain tax positions on the bases of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

***Recently Issued or Adopted Accounting Pronouncements***

In April 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-08, “*Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment*”

## ORTHOPEDIATRICS CORP.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2014 and 2015

(in thousands, except share information)

## NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

(Topic 360),” which includes amendments that change the requirements for reporting discontinued operations and require additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations that have, or will have, a major effect on the organization’s operations and financial results should be presented as discontinued operations. Additionally, this guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The standard is applied prospectively and is effective for public entities beginning in annual periods after December 15, 2014, and interim periods within those years, with early adoption permitted. We adopted the guidance in the first quarter of 2014. This adoption did not have a material impact on our consolidated financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU 2014-15, “*Presentation of Financial Statements — Going Concern (Subtopic 205-40)*.” The new guidance addresses management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We do not expect to early adopt this guidance and does not believe that the adoption of this guidance will have a material impact on our consolidated financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU 2015-03, “*Interest — Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*.” This update requires an entity to present debt issuance costs related to a recognized debt liability as a direct deduction from the carrying amount of that debt liability consistent with debt discounts and is effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. We do not expect it to have a material impact on our consolidated financial position, results of operations or cash flows.

In July 2015, the FASB issued ASU 2015-11 “*Simplifying the Measurement of Inventory*,” which is intended to narrow down the alternative methods available for valuing inventory. The new guidance does not apply to inventory currently measured using the last-in-first-out (“LIFO”) or the retail inventory valuation methods. Under the new guidance, inventory valued using other methods, including the first-in-first-out method, must be valued at the lower of cost or net realizable value. This guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We do not believe the guidance will have a material impact on our consolidated financial position, results of operations and cash flows.

In May 2014, the FASB issued ASU 2014-09 “*Revenue from Contracts with Customers*,” on the recognition of revenue for all contracts with customers designed to improve comparability and enhance financial statement disclosures. The underlying principle of this comprehensive model is that revenue is recognized to depict the transfer of promised goods or services to customers in an amount that reflects the payment to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB subsequently issued guidance which approved a one year deferral of the guidance for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017. Early adoption is permitted as of the original effective date for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. We are currently evaluating the impact of this guidance on our consolidated financial position, results of operations and cash flows.



**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

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**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)**

In November 2015, the FASB issued ASU 2015-07 “*Balance Sheet Classification of Deferred Taxes*,” which provides guidance on the balance sheet classification of deferred taxes. Under the current guidance, deferred tax liabilities and assets must be separated into current and noncurrent amounts in a classified statement of financial position. The new guidance requires deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The new guidance does not change the requirement that deferred tax liabilities and assets of a tax-paying component of an entity to be offset and presented as a single amount. The guidance is effective for our fiscal year 2019 annual financial statements and for interim periods within our fiscal year 2020, with earlier application permitted as of the beginning of an interim or annual reporting period. The guidance offers two acceptable adoption methods: (i) retrospective adoption to all periods presented; or (ii) prospective adoption to all deferred tax liabilities and assets. As this standard only changes the classification of current deferred tax assets and liabilities to noncurrent assets and liabilities, we do not believe the adoption of this standard will have a material effect on our financial position, results of operations, or cash flows.

**NOTE 3 — PROPERTY AND EQUIPMENT, NET**

Property and equipment, net consisted of the following at December 31:

	2014	2015
Land	\$ 1,435	\$ 1,435
Building and building improvements	1,047	1,047
Computer equipment and software	1,307	1,423
Office and other equipment	346	373
Instruments	5,823	7,095
Sample inventory	871	1,013
Construction in progress	1,072	1,186
	11,901	13,572
Less: accumulated depreciation	(4,434)	(6,236)
Total property and equipment, net	<u>\$ 7,467</u>	<u>\$ 7,336</u>

Depreciation expense was \$1,556 and \$1,848 in 2014 and 2015, respectively, and is included in general and administrative expenses.

**NOTE 4 — INTANGIBLE ASSETS**

As of December 31, 2015, the balances of amortizable intangible assets were as follows:

	Weighted-Average Amortization Period	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Patents	13.5 years	\$ 127	\$ (41)	\$ 86
License Agreements		541	—	541
Total amortizable assets		<u>\$ 668</u>	<u>\$ (41)</u>	<u>\$ 627</u>

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

*(in thousands, except share information)*

**NOTE 4 — INTANGIBLE ASSETS — (continued)**

As of December 31, 2014, the balances of amortizable intangible assets, were as follows:

	Weighted-Average Amortization Period	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Patents	14.5 years	\$ 127	\$ (35)	\$ 92
License agreements		500	—	500
Total amortizable assets		<u>\$ 627</u>	<u>\$ (35)</u>	<u>\$ 592</u>

Amortization expense was \$6 in both 2014 and 2015. At December 31, 2015, the future estimated amortization on the above amortizable intangible assets is expected to be \$31 in 2016 and \$58 annually for 2017 through 2021.

Licenses are tied to product launches and do not begin amortizing until the product is launched to the market. Anticipated market launch is in 2016 and 2017 for products for which we obtained licensing.

Trademarks are non-amortizing intangible assets which had a value of \$260 as of December 31, 2014 and 2015.

**NOTE 5 — ACCRUED COMPENSATION AND BENEFITS**

As of December 31, 2014 and 2015, accrued compensation and benefits consisted of the following:

	2014	2015
Accrued compensation and related costs	\$ 868	\$ 1,265
Accrued commissions	616	992
Total accrued compensation and benefits	<u>\$ 1,484</u>	<u>\$ 2,257</u>

**NOTE 6 — DEBT AND CREDIT ARRANGEMENTS**

As of December 31, 2014 and 2015, long-term debt consisted of the following:

	2014	2015
Note payable to Squadron	\$ 11,401	\$ 11,401
Mortgage payable to affiliate	1,837	1,739
Total debt	13,238	13,140
Less: current maturities	97	101
Long-term debt, net of current maturities	<u>\$ 13,141</u>	<u>\$ 13,039</u>

In May 2014, we entered into the Second Amended and Restated Loan and Security Agreement with Squadron in connection with a restructuring of our debt and equity. The terms of this agreement require monthly interest only payments computed at 10% per annum with all principal and unpaid interest due at maturity in May 2017 or earlier upon a change of control event, as defined in the agreement. The note is secured by substantially all of our assets. In November 2015, this agreement was amended to provide a revolving loan commitment of an additional \$7,000. The revolving loan commitment is structured under the same terms and conditions with interest payable monthly computed at 10% per annum and principal due at maturity in May 2017. As of December 31, 2015, there are no borrowings outstanding under the revolving loan commitment.

In connection with the purchase of our office and warehouse space in Warsaw, Indiana in August 2013, we entered into a mortgage note payable to Tawani Enterprises Inc., an affiliate of Squadron. Pursuant to the terms of the mortgage note, we pay Tawani Enterprises Inc. monthly principal and interest

**ORTHOPEDIATRICS CORP.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****For the years ended December 31, 2014 and 2015***(in thousands, except share information)***NOTE 6 — DEBT AND CREDIT ARRANGEMENTS – (continued)**

installments of \$16 with interest compounded at 5% until maturity in 2028, at which time a final payment of remaining principal and interest is due. The mortgage is secured by the related real estate and building. As of December 31, 2014 and 2015, the mortgage balance was \$1,837 and \$1,739, of which current principal due of \$97 and \$101, respectively, was included in current portion of long-term debt.

At December 31, 2015, the aggregate future principal payments on this debt was as follows:

Year Ending December 31:

2016	\$	101
2017		11,506
2018		112
2019		118
2020		124
Thereafter		1,179
	\$	<u>13,140</u>

In May 2014, we completed a restructuring of our outstanding debt with Squadron. At the time of restructuring, we had outstanding indebtedness and accrued interest under the First Amended and Restated Loan Agreement totaling \$33,518, at interest rates ranging from 10% to 14% per annum and maturity dates ranging from May 2014 to September 2018. In connection with this restructuring, we converted \$22,030 of outstanding indebtedness and \$510 of accrued interest into shares of Series B Redeemable Convertible Preferred Stock (Note 10). The terms of the remaining outstanding indebtedness of \$11,401 was restructured under the Second Amended and Restated Loan and Security Agreement. No gain or loss was recognized as the fair value of the new instruments was equal to the carrying value of the debt extinguished.

During 2014, we paid in full convertible promissory notes to two individuals totaling \$520.

The fair value of our note payable to Squadron was estimated based on prices for the same or similar issues and the current interest rates offered for the debt of the same remaining maturities, which are considered level 2 inputs in accordance with ASC Topic 820, "Fair Value Measurements and Disclosures." At December 31, 2015, the fair value approximated the carrying value.

Interest expense relating to notes payable to Squadron totaled \$2,549 and \$1,230 in 2014 and 2015, respectively.

**NOTE 7 — STRATEGIC ARRANGEMENTS**

Effective December 1, 2007, we entered into a ten year agreement with Case Western Reserve University ("CASE") to assist in certain aspects of our research and development. The main focus of this research and development involves leveraging our exclusive rights to the Hamann-Todd Collection of the Cleveland National History Museum, the world's largest pediatric osteological collection, to assist in the design of implants which match pediatric bone curvature and structure.

In exchange for services, CASE receives certain royalties and up-front fees. The royalties and certain fees are contingent upon our obtaining FDA approval and the launch of our products into the marketplace. CASE receives a minimum annual royalty of \$10 or a royalty of 3% of net sales on products, whichever is greater. Additionally, for each new product developed, CASE will receive milestone payments of \$5 for FDA approval to sell our products within the United States and a milestone payment of \$10 for general product launch. Additionally, CASE receives a royalty of 3% of net sales on products fully developed and being sold in the marketplace.

## ORTHOPEDIATRICS CORP.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2014 and 2015

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**NOTE 7 — STRATEGIC ARRANGEMENTS – (continued)**

The royalty expense recognized related to the CASE agreement amounted to \$113 and \$120 in 2014 and 2015, respectively, and is recorded as a component of cost of revenue. As of December 31, 2014 and 2015, \$28 and \$26, respectively, was due to CASE, and is recorded in other current liabilities.

**NOTE 8 — INCOME TAXES**

The components of income tax expense (benefit) for the years ended December 31, 2014 and 2015 are as follows:

	2014	2015
Deferred:		
Federal	\$(3,194)	\$ (2,562)
State	(433)	(325)
	(3,627)	(2,887)
Increase in valuation allowance	3,627	2,887
Total tax expense	\$ —	\$ —

The reconciliation between the effective tax rate and the statutory tax rate is as follows:

	2014	2015
Federal statutory rate	34.0%	34.0%
State statutory rate, net of federal benefit	4.2	4.2
Nondeductible/nontaxable items	(0.5)	(0.7)
Change in valuation allowance	(37.7)	(37.5)
Income tax expense (benefit)	0.0%	0.0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The primary temporary differences that give rise to the deferred tax assets and liabilities are certain inventory adjustments, amortization, research and development fees, and net operating loss carryforwards.

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

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**NOTE 8 — INCOME TAXES – (continued)**

The deferred tax assets and liabilities consisted of the following at December 31, 2014 and 2015:

	2014	2015
Deferred tax assets:		
Research and development fee obligation	\$ 787	\$ 580
Inventories, net	2,124	2,439
Loss carryforwards	20,241	23,059
Credit carryforwards	176	176
Other	118	149
	<u>23,446</u>	<u>26,403</u>
Valuation allowance	(23,038)	(25,925)
Total deferred tax assets	408	478
Deferred tax liabilities:		
Intangibles	(359)	(429)
Property, plant and equipment	(49)	(49)
Total deferred tax liabilities	<u>(408)</u>	<u>(478)</u>
Deferred tax assets, net	<u>\$ —</u>	<u>\$ —</u>

The deferred tax assets were fully offset by a valuation allowance at December 31, 2014 and 2015, and no income tax benefit has been recognized in our consolidated statements of operations for each of the years then ended. At December 31, 2015, we had available federal and state tax loss carryforwards of \$60,323 and tax credits for federal and state tax purposes of \$176 which begin to expire in 2028. Sections 382 and 383 of the Internal Revenue Code subject the utilization of net operating loss and credit carryforwards to an annual limitation that is applicable if we experience an ownership change. We believe our prior equity transactions may have triggered an ownership change as defined by the Internal Revenue Code, but we have not yet completed the computations under Sections 382 and 383.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2015. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth.

We are subject to taxation in the United States and Indiana. As of December 31, 2015, all tax years from 2008 remain open to examination by the major taxing jurisdictions to which we are subject due to our net operating loss and credit carryforwards from those years. We believe that the income tax filing positions will be sustained on audit and do not anticipate any adjustments that will result in a material change. Therefore, no reserve for uncertain income tax positions has been recorded. Interest and penalties, if any, associated with income tax examinations will be to record such items as a component of income taxes.

**NOTE 9 — STOCKHOLDERS' DEFICIT**

***Stock Options***

The fair value for options granted at the time of issuance were estimated at the date of grant using a Black-Scholes options pricing model. Significant assumptions included in the option value model include the fair value of our common stock at the grant date, weighted average volatility, risk-free interest rate, dividend yield and the forfeiture rate. There were no stock options granted in 2014 or 2015.

**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

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**NOTE 9 — STOCKHOLDERS' DEFICIT – (continued)**

Our stock option activity in 2014 and 2015 and related information are summarized as follows:

	<u>Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Terms (in Years)</u>
Outstanding at December 31, 2013	438,139	\$ 15.93	4.6
Exercised	(4,800)	\$ 6.25	
Forfeited or expired	(55,482)	\$ 15.45	
Outstanding at December 31, 2014	377,857	\$ 16.01	4.3
Forfeited or expired	(6,408)	\$ 18.85	
Outstanding at December 31, 2015	<u>371,449</u>	\$ 15.96	3.4

Options generally include a time-based vesting schedule permitting the options to vest ratably over three years. As of December 31, 2015, all options were fully vested.

Stock-based compensation expense on stock options amounted to \$26 and \$0 in 2014 and 2015, respectively.

***Restricted Stock***

Our restricted stock activity in 2014 and 2015 and related information are summarized as follows:

	<u>Restricted Stock</u>	<u>Weighted-Average Remaining Contractual Terms (in Years)</u>
Outstanding at December 31, 2013	284,775	3.7
Granted	110,538	
Forfeited	(5,984)	
Outstanding at December 31, 2014	389,329	3.2
Granted	497,641	
Forfeited	(920)	
Outstanding at December 31, 2015	<u>886,050</u>	4.3
Restricted stock exercisable at December 31, 2015	<u>—</u>	

As of December 31, 2015, there was \$5,010 of unrecognized compensation expense remaining related to our service-based restricted stock awards. The cost is expected to be recognized over a weighted average period of 4.3 years, or earlier upon elimination of the restriction period as a result of an initial public offering or change in control event.

Stock-based compensation expense on restricted stock amounted to \$680 and \$1,229 in 2014 and 2015, respectively. Due to our limited operating history and lack of marketability, a discount of 24% and 18% was applied when estimating the stock based compensation for restricted stock in 2014 and 2015, respectively.

Total stock compensation expense was \$706 and \$1,229 in 2014 and 2015, respectively, and is included as a component of general and administrative expenses in our results of operations.

ORTHOPEDIATRICS CORP.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2014 and 2015

(in thousands, except share information)

NOTE 9 — STOCKHOLDERS' DEFICIT – (continued)

**Warrants**

At December 31, 2014 and 2015, there were warrants issued and outstanding for the issuance of 65,823 shares of common stock. The warrants were issued from 2008 to 2012 at exercise prices ranging from \$17.60 to \$20.75 per share. The warrants generally have a ten-year term. As of December 31, 2014 and 2015, no warrants had been exercised. At inception, no fair value was assigned to the warrants.

NOTE 10 — REDEEMABLE CONVERTIBLE PREFERRED STOCK

We have authorized 7,000,000 shares of redeemable convertible preferred stock, of which 5,446,978 shares were issued and outstanding as of December 31, 2014 and 2015, designated in series, with the rights and preferences of each designated series determined by the Board of Directors.

Redeemable convertible preferred stock as of December 31, 2014 and 2015 consisted of the following:

Series	Preferred Shares Authorized	Initial Year of Issuance	Shares Issued and Outstanding	Per Share Liquidation Preference <sup>(1)</sup>	Aggregate Liquidation Preference <sup>(1)</sup>	Carrying Value	
						2014	2015
A	1,000,000	2011	1,000,000	\$ 21.65	\$ 21,654	\$ 20,005	\$ 21,654
B	6,000,000	2014	4,446,978	\$ 1.10	4,879	40,625	43,773
Totals	7,000,000		5,446,978		\$ 26,533	\$ 60,630	\$ 65,427

(1) Amounts are calculated based on mandatory conversion preference in the event of an initial public offering or change in control event, as defined.

In May 2014, we completed an initial issuance of Series B preferred stock that included conversion of indebtedness due to Squadron, and accrued interest thereon, of \$22,030 and \$510, respectively, to shares of Series B preferred stock. Simultaneously with this conversion of indebtedness Squadron, along with other investors, purchased Series B preferred stock for cash totaling \$16,864. In connection with the issuance of the Series B preferred stock, we entered into an amended and restated certificate of designations, preferences and rights of preferred stock, or the Preferred Stock Terms.

*Dividend and Liquidation Rights*

Pursuant to the Preferred Stock Terms, Series A and B preferred stock, with respect to dividend and liquidation rights, rank senior to common stock. The holders of the Series A and B preferred stock are entitled to receive dividends at the per annum rate of 8% of the original purchase price (\$16.00 and \$8.77 per share for Series A and B, respectively), as defined. Such dividends are cumulative and compounded on a quarterly basis. Any dividends paid with respect to the shares of Series A and B preferred stock are paid pro rata to the preferred stockholders. For the years ended December 31, 2014 and 2015, accretion of dividends of the preferred stock to redemption value was \$3,255 and \$4,797, respectively, which was recognized as a reduction to additional paid-in capital.

In the event of a voluntary or involuntary liquidation of our company, the holders of the preferred stock, before any payment to the holders of common stock or other junior securities, are entitled to an amount equal to the sum of the original Series A or Series B issue price and all accrued but unpaid dividends.

In addition to the preferred dividend rights, the holders of the Series A and B preferred stock are entitled to participate fully in any dividends or distributions to common shareholders, after payment of any cumulative and unpaid preferred dividend, on a pro rata basis with the common shareholders.

ORTHOPEDIATRICS CORP.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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**NOTE 10 — REDEEMABLE CONVERTIBLE PREFERRED STOCK – (continued)**

*Conversion Rights*

Each share of the Series A and B preferred stock is convertible at any time, at the option of the holder, into shares of common stock on a 1:1 conversion ratio. The Preferred Stock Terms also provide the holders of the preferred stock various anti-dilution and down round protection provisions designed to maintain the conversion ratio. If converted into common shares, the holders of the preferred stock are entitled to receive payment of all accumulated and unpaid dividends at the time of such conversion.

The Preferred Stock Terms require mandatory conversion of the Series A and Series B preferred stock in connection with a qualified initial public offering or change in control, as defined. In addition to the conversion to common stock upon mandatory conversion, the holders of Series A preferred stock are entitled to receive a payment equal to the original Series A issue price and all accrued but unpaid dividends, and the holders of the Series B preferred stock are entitled to receive a payment equal to 50% of the current accumulated but unpaid dividends.

*Redemption Rights*

The Series A and B preferred stock is redeemable at the option of the holders at any time on or after May 30, 2017 upon approval of at least 51% of the holders of the preferred stock acting as a single class. Upon redemption, the holders of the preferred stock are entitled to receive cash payment equal to the greater of (i) the sum of the original Series A or Series B issue price and all accrued but unpaid dividends or (ii) fair market value, as defined in the Preferred Stock Terms.

*Board of Directors and Voting Rights*

The Preferred Stock Terms provide holders of our Series A preferred stock, and shares of our common stock issued upon the conversion thereof, with the right, exclusively and as a separate class, to elect one member of our Board of Directors; and provide holders of our Series B preferred stock, and shares of our common stock issued upon the conversion thereof, with the right, exclusively and as a separate class, to elect two members of our Board of Directors. In addition, the holders of our Series A and Series B preferred stock may vote such shares as if they were converted to shares of common stock based on a 1:1 conversion ratio.

**NOTE 11 — NET LOSS PER SHARE**

The following is a reconciliation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2014 and 2015:

	2014	2015
Net loss	\$ (9,549)	\$ (7,891)
Accretion of cumulative dividends of redeemable preferred stock to redemption value	(3,255)	(4,797)
Net loss attributable to common stockholders – basic and diluted	\$ (12,804)	\$ (12,688)
Weighted average number of shares – basic and diluted	2,603,425	2,603,517
Net loss per share attributable to common stockholders – basic and diluted <sup>(1)</sup>	\$ (4.92)	\$ (4.87)

(1) The effect of discontinued operations on loss per share has been excluded for 2014 and 2015 as it is not material.



**ORTHOPEDIATRICS CORP.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2014 and 2015**

*(in thousands, except share information)*

**NOTE 11 — NET LOSS PER SHARE – (continued)**

Our basic and diluted net loss per share is computed using the two-class method. The two-class method is an earnings allocation that determines net income per share for each class of common stock and participating securities according to their participation rights in dividends and undistributed earnings or losses. Non-vested restricted stock that include non-forfeitable rights to dividends are considered participating securities. Series A and B preferred stock include rights to participate in dividends and distributions to common shareholders on an if-converted basis, and accordingly are also considered participating securities. During periods of undistributed losses however, no effect is given to our participating securities since they are not contractually obligated to share in the losses.

Because we have reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share. The following contingently issuable and convertible equity shares were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the years ended December 31, 2014 and 2015 (shares for the redeemable convertible preferred shares were determined based on the applicable conversion ratio of 1:1):

	<u>2014</u>	<u>2015</u>
Redeemable convertible preferred stock – Series A	1,000,000	1,000,000
Redeemable convertible preferred stock – Series B	4,446,978	4,446,978
Restricted stock	389,329	886,050
Stock options	377,857	371,449
Warrants	65,823	65,823
	<u>6,279,987</u>	<u>6,770,300</u>

*Unaudited Pro Forma Net Loss Per Share*

Unaudited pro forma basic and diluted loss per share attributable to common shareholders are computed as follows:

**NOTE 12 — BUSINESS SEGMENT**

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. We have one operating and reporting segment, OrthoPediatrics, which designs, develops and markets anatomically appropriate implants and devices for children with orthopedic problems. Our chief operating decision-maker, our Chief Executive Officer, reviews financial information presented on a consolidated basis for purposes of making operating decisions and assessing financial performance, accompanied by disaggregated revenue information by product category. We do not assess the performance of our individual product categories on measures of profit or loss, or other asset-based metrics. Therefore, the information below is presented only for revenue by category and geography.

Product sales attributed to a country or region includes product sales to hospitals, physicians and distributors and is based on the final destination where the products are sold. No individual customer accounted for more than 10% of total product sales for 2014 or 2015. One customer accounted for 11% of consolidated accounts receivable as of December 31, 2014 and no customers accounted for more than 10% of consolidated accounts receivable as of December 31, 2015.

**ORTHOPEDIATRICS CORP.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****For the years ended December 31, 2014 and 2015***(in thousands, except share information)***NOTE 12 — BUSINESS SEGMENT – (continued)**

Product sales by source were as follows for the years ended December 31, 2014 and 2015:

	2014	2015
Product sales by geographic location:		
U.S.	\$ 18,421	\$ 24,910
International	5,263	6,094
Total	<u>\$ 23,684</u>	<u>\$ 31,004</u>
	2014	2015
Product sales by category:		
Trauma and deformity	\$ 19,325	\$ 22,475
Spine	3,556	7,446
ACL reconstruction/other	803	1,083
Total	<u>\$ 23,684</u>	<u>\$ 31,004</u>

No individual country with sales originating outside of the United States accounted for more than 10% of consolidated revenue in 2014 or 2015.

**NOTE 13 — RELATED PARTY TRANSACTIONS**

In addition to the debt and credit agreements and mortgage with Squadron and its affiliate (refer to Note 6), we currently use FMI Hansa Medical Products, LLC and Structure Medical, LLC as two of our suppliers. Each of these entities is affiliated with Squadron. We do not have long-term contracts with either supplier. For the years ended December 31, 2014 and 2015, we made payments to FMI Hansa Medical Products, LLC of \$1,363 and \$320, respectively, and Structure Medical, LLC of \$2,247 and \$880, respectively.

**NOTE 14 — EMPLOYEE BENEFIT PLAN**

We have a defined-contribution plan, OrthoPediatics 401(k) Retirement Plan (the “401(k) Plan”), which includes a cash or deferral (Section 401(k)) arrangement. The 401(k) Plan covers those employees who meet certain eligibility requirements and elect to be participants in the 401(k) Plan. Employee contributions are limited to the annual amounts permitted under the Internal Revenue Code. The 401(k) Plan allows us to make a discretionary matching contribution. Discretionary matching contributions are determined annually by management. We did not make a discretionary matching contribution for the years ended December 31, 2014 or 2015.

**ORTHOPEDIATRICS CORP.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****For the years ended December 31, 2014 and 2015***(in thousands, except share information)***NOTE 15 — DISCONTINUED OPERATIONS**

In 2014, we made a strategic business decision to no longer sell biologics products to our customers. The revenue, cost of goods sold and expenses were all netted together and the gain or loss was reported as (gain) loss from discontinued operations on our statements of operations. As of December 31, 2015, we had liquidated the entire biologics product line. The related results of discontinued operations are presented below at and for the years ended December 31:

	2014	2015
Assets held for sale at year end	\$ 577	\$ —
Revenue	\$ 845	\$ —
Expenses	634	—
Results from operating activities	211	—
Loss on sale of assets held for sale	—	38
Loss (gain) from discontinued operations	\$ (211)	\$ 38

**NOTE 16 — COMMITMENTS AND CONTINGENCIES**

We are involved with various legal actions arising in the ordinary course of our activities. We accrue for those cases where the potential liability is estimable and probable. We are not presently a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate materially affect our financial position or results of operations or cash flows.

As of December 31, 2015, we are contracted to pay royalties to individuals and entities that provide research and development services, which range from 0.5% to 6% of sales. Additionally, we have minimum royalty commitments of \$84 annually through 2020.

We have products in development that have milestone payments and royalty commitments. In any development project, there are significant variables that will affect the amount and timing of these payments and as of December 31, 2015, we have not been able to determine the amount and timing of payments. We do not anticipate these future payments will have a material impact on our financial results.

**Shares**

**ORTHOPEDIATRICS CORP.**

**Common Stock**



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**PROSPECTUS**

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**Piper Jaffray**

**Stifel**

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**William Blair**

, 2016

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the NASDAQ listing fee.

<b>Item</b>	<b>Amount</b>
SEC Registration Fee	\$ *
FINRA Filing Fee	*
NASDAQ Listing Fee	*
Legal Fees and Expenses	*
Accountants' Fees and Expenses	*
Printing and Engraving Expenses	*
Blue Sky Fees and Expenses	*
Transfer Agent and Registrar's Fees and Expenses	*
Miscellaneous Expenses	*
Total	\$ *

\* To be provided by amendment.

**Item 14. Indemnification of Directors and Officers**

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, will provide that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

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Our amended and restated certificate of incorporation will provide that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnatee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnatee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation will provide that we will indemnify any Indemnatee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnatee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnatee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnatee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnatee under certain circumstances.

We intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

### **Item 15. Recent Sales of Unregistered Securities**

Set forth below is information regarding shares of capital stock issued by us since January 1, 2013. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

#### *(a) Issuances of Capital Stock*

On April 16, 2013 and August 26, 2013, we issued an aggregate of 36,144 shares of our common stock to two investors for a purchase price of \$20.75 per share, or approximately \$750,000. On May 30, 2014, we issued an aggregate of 4,446,978 shares of our Series B Preferred Stock to 39 investors, including Squadron Capital, LLC, for a purchase price of \$8.77 per share, or approximately \$39 million.

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No underwriters were involved in the foregoing sales of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of convertible preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

### *(b) Grants and Exercise of Stock Options*

On September 10, 2013, we granted stock options to purchase an aggregate of 9,400 shares of our common stock at a weighted average exercise price of \$20.75 per share, to certain of our employees and directors in connection with services provided to us by such persons. Of these, no options have been exercised through December 31, 2015.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

## **Item 16. Exhibits and Financial Statement Schedules**

### **(a) Exhibits**

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

### **(b) Financial Statement Schedules**

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## **Item 17. Undertakings**

The undersigned registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.



### SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chicago, State of Illinois, on this       day of       , 2016.

ORTHOPEDIATRICS CORP.

By: \_\_\_\_\_  
Mark C. Throdahl  
*President and Chief Executive Officer*

### POWER OF ATTORNEY

We, the undersigned officers and directors of OrthoPediatics Corp., hereby severally constitute and appoint Mark C. Throdahl and Fred L. Hite, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him or her and in his or her name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
	President and Chief Executive Officer	, 2016
Mark C. Throdahl	(Principal Executive Officer)	
	Chief Financial Officer	, 2016
Fred L. Hite	(Principal Financial and Accounting Officer)	
	Chairman of the Board	, 2016
Terry D. Schlotterback		
	Director	, 2016
Berne B. Berry, III		
	Director	, 2016
Bryan W. Hughes		
	Director	, 2016
Marie C. Infante		
	Director	, 2016
Alan Kozlowski		

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Signature	Title	Date
	Director	, 2016
Oscar Moralez		
	Director	, 2016
Peter J. Munson		
	Director	, 2016
David R. Pelizzon		
	Director	, 2016
Kevin L. Unger		

## EXHIBIT INDEX

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1**	Certificate of Incorporation of the Registrant, as currently in effect
3.2**	Certificate of Amendment of Certificate of Incorporation of the Registrant, dated as of May 28, 2014
3.3**	By-laws of the Registrant, as currently in effect
3.4**	Amended and Restated Certificate of Designations, Preferences and Rights of Preferred Stock, as currently in effect
3.5*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be effective immediately prior to the completion of this offering
3.6*	Form of Amended and Restated Bylaws of the Registrant, to be effective immediately prior to the completion of this offering
4.1*	Specimen stock certificate evidencing the shares of common stock
4.2**	Registration Rights Agreement, by and between the Registrant and Squadron, dated as of May 30, 2014
4.3*	Stockholders Agreement
5.1*	Opinion of Latham & Watkins LLP
10.1#*	Form of Director and Executive Officer Indemnification Agreement
10.2#**	Amended and Restated 2007 Equity Incentive Plan
10.3#**	2016 Incentive Award Plan and forms of option agreements thereunder
10.4#*	Independent Director Compensation Policy
10.5#**	Employment Agreement, by and between the Registrant and Mark C. Throdahl, dated as of July 31, 2014
10.6#**	Employment Agreement, by and between the Registrant and Fred L. Hite, dated as of February 1, 2015
10.7#**	Employment Agreement, by and between the Registrant and David R. Bailey, dated as of July 31, 2014
10.8#**	Employment Agreement, by and between the Registrant and Gregory A. Odle, dated as of July 31, 2014
10.9#**	Employment Agreement, by and between the Registrant and Daniel J. Gerritzen, dated as of July 31, 2014
10.10**	Second Amended and Restated Loan and Security Agreement, by and among the Registrant, OrthoPediatrics US Distribution Corp. and Squadron, dated as of May 30, 2014
10.11**	Term Note, by and between the Registrant and Squadron, dated as of May 30, 2014
10.12**	First Amendment to Second Amended and Restated Loan and Security Agreement, by and among the Registrant, OrthoPediatrics US Distribution Corp. and Squadron, dated as of November 19, 2015
10.13**	Revolving Note, by and among the Registrant, OrthoPediatrics US Distribution Corp. and Squadron, dated as of November 19, 2015
21.1**	Subsidiaries of the Registrant
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
23.3	Consent of Life Science Intelligence, Inc.
24.1**	Power of Attorney (included on signature page)

\* To be filed by amendment

\*\* Previously filed

# Management contract or compensatory plan

## CONSENT OF LIFE SCIENCE INTELLIGENCE, INC.

We hereby consent to (1) the use of and references to our name in the prospectus included in the registration statement on Form S-1 of OrthoPediatrics Corp. (the “Company”) and any amendments thereto (the “Registration Statement”), including, but not limited to, under the “Summary,” “Market and Industry Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” sections, and (2) the filing of this consent as an exhibit to the Registration Statement by the Company for the use of our data and information cited in the above-mentioned sections with data reference points outlined and described expressly within Schedule I hereto only. Any data or information not appearing within Schedule I hereto is not authorized for use and does not form part of this consent exhibit.

The data and information used in the Registration Statement, including, but not limited to, under the “Summary,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” sections and described on Schedule I hereto, are obtained from our report titled: U.S. Anterior Cruciate Ligament Reconstruction Procedure Volume Analysis.

By: /s/ Scott Pantel  
Scott Pantel  
President  
Life Science Intelligence, Inc.

April 20, 2016

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## Schedule I

The information listed below and appearing in the “Summary” section of the prospectus:

We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

The information listed below and appearing in the “Market and Industry Data” section of the prospectus:

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations. Life Science Intelligence, Inc., the primary source for anterior cruciate ligament procedural data included in this prospectus, was commissioned by us to compile this information. In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

The information listed below and appearing in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of the prospectus:

We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

The information listed below and appearing in the “Business” section of the prospectus:

We estimate that the portion of this market that we currently serve represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

We currently serve a portion of the pediatric orthopedic implant market that we estimate represented a \$1.4 billion opportunity globally in 2015, including nearly \$800 million in the United States.

The chart below provides the estimated sizes of the three categories of our U.S. addressable market opportunity based on third party data (including ACL Reconstruction data compiled by Life Science Intelligence Inc. in a study that we commissioned) regarding the number of procedures performed in 2015 and our average revenue per procedure:

U.S. Pediatric Orthopedic Implant Market	ACL Reconstruction	
	\$	102 Million

According to Life Science Intelligence, Inc., in a study that we commissioned, approximately 29% of ACL reconstruction procedures completed in the United States in 2015 were in patients under the age of 18. The vast majority of these procedures were performed in ambulatory surgery centers.

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