

AMEDICA Corp  
Form S-3  
November 25, 2016

**As filed with the Securities and Exchange Commission on November 25, 2016**

**Registration No. 333-**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM S-3**

**REGISTRATION STATEMENT**

***UNDER***

***THE SECURITIES ACT OF 1933***

**AMEDICA CORPORATION**

**(Exact name of registrant as specified in its charter)**

**Delaware                                      84-1375299**  
**(State or other jurisdiction of      (I.R.S. Employer**

**incorporation or organization) Identification No.)**

**1885 West 2100 South**

**Salt Lake City, UT 84119**

**(801) 839-3500**

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

**B. Sonny Bal, MD**

**President and Chief Executive Officer**

**Amedica Corporation**

**1885 West 2100 South**

**Salt Lake City, UT, 84119**

**(801) 839-3500**

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

*Copies to:*

**David F. Marx**

**Dorsey & Whitney LLP**

**136 South Main Street, Suite 1000**

**Salt Lake City, Utah 84101**

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. [ ]

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 [ ] Accelerated filer [ ]  
Non-accelerated filer [ ] (Do not check if a smaller reporting company) Smaller reporting company [X]

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities To Be Registered</b>	<b>Amount to be Registered(1)</b>	<b>Proposed Maximum Offering Price Per Share(2)</b>	<b>Proposed Maximum Aggregate Offering Price(2)</b>	<b>Amount of Registration Fee</b>
Common Stock, \$0.01 par value per share	962,380	\$ 0.85	\$ 818,023	\$ 94.81

Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of (1) common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities

Act. The price per share and aggregate offering price are based on the average of the high and low prices of the registrant's common stock on November 18, 2016, as reported on the NASDAQ Capital Market.

**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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, Dated November 25, 2016**

## **PROSPECTUS**

**962,380 Shares**

## **AMEDICA CORPORATION**

### **Common Stock**

This prospectus relates to the sale or other disposition from time to time of up to 962,380 shares of our common stock held by the selling stockholders named in this prospectus. The shares of common stock covered by this prospectus were previously issued by us in a private placement, which is more fully described in the section titled “Prospectus Summary—The Offering” on page 4. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale or other disposition of shares by the selling stockholders.

The selling stockholders may sell or otherwise dispose of the shares of common stock covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock in the section entitled “Plan of Distribution” on page 24. Discounts, concessions, commissions and similar selling expenses attributable to the sale of shares of common stock covered by this prospectus will be borne by a selling stockholder. We will pay all expenses (other than discounts, concessions, commissions and similar selling expenses) relating to the registration of the shares with the Securities and Exchange Commission.

Our common stock is traded on The NASDAQ Capital Market under the symbol “AMDA.” On November 23, 2016, the last reported sales price of our common stock was \$0.71 per share.

*Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 4 of this prospectus, and under similar headings in any amendment or supplements to this prospectus or as updated by any subsequent filing with the Securities and Exchange Commission that is incorporated by reference herein.*

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

**The date of this prospectus is \_\_\_\_\_, 2016.**

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## ABOUT THIS PROSPECTUS

**You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with additional or different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.**

**Unless the context requires otherwise, all references to “we”, “us”, “our”, “Amedica” or the “Company” in this prospectus are to Amedica Corporation. “Amedica,” “CSC,” “MC2,” “Valeo” and “rethink what’s possible” are registered U.S. trademarks of Amedica Corporation. “US Spine” is a registered U.S. trademark of our subsidiary, US Spine, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.**





## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our common stock. You should read this entire prospectus carefully, including the section entitled “Risk Factors” and the documents that we incorporate by reference into this prospectus, before making an investment decision.*

### Background Information

We are a materials company focused on developing, manufacturing and selling silicon nitride ceramics that are used in medical implants and in a variety of industrial devices. At present, we commercialize silicon nitride in the spine implant market. We believe that our facile silicon nitride manufacturing expertise positions us favorably to introduce new and innovative devices in the medical and non-medical fields. We also believe that we are the first and only company to commercialize silicon nitride medical implants.

We have received 510(k) regulatory clearance in the United States, a CE mark in Europe, and ANVISA approval in Brazil for a number of our devices that are designed for spinal fusion surgery. To date, more than 25,000 of our silicon nitride devices have been implanted into patients, with an 8-year successful track record. We have a pending FDA 510(k) submission for clearance in the United States of a novel composite spinal fusion device that combines porous and solid silicon nitride, and obviates the need for bone grafts. In February 2016, the FDA sent us questions about our clinical study, and we are currently in the process of submitting a response.

We believe that silicon nitride has a superb combination of properties that make it ideally suited for human implantation. Other biomaterials are based on bone grafts, metal alloys, and polymers; all of which have practical limitations. In contrast, silicon nitride has a legacy of success in the most demanding and extreme industrial environments. As a human implant material, silicon nitride offers bone ingrowth, resistance to bacterial infection, resistance to corrosion, superior strength and fracture resistance, and ease of diagnostic imaging, among other advantages.

We market and sell our Valeo brand of silicon nitride implants to surgeons and hospitals in the United States and to selected markets in Europe and South America through more than 50 independent sales distributors who are supported by an in-house sales and marketing management team. These implants are designed for use in cervical (neck) and thoracolumbar (lower back) spine surgery. We recently entered into a 10-year exclusive distribution agreement with Shandong Weigao Orthopaedic Device Company Limited (“Weigao”) to sell Amedica-branded silicon nitride spinal fusion devices within the People’s Republic of China (“China”). Weigao, a large orthopedic company, has expertise in acquiring Chinese Food and Drug Administration (“CFDA”) approval of medical devices, and will assist us in obtaining

regulatory approval. Weigao has committed to minimum purchase requirements totaling 225,000 implants in the first six years following CFDA clearance. We are also working with other partners in Japan to obtain regulatory approval for silicon nitride in that country. China and Japan are relevant because historically, ceramic implants are more familiar to, and more readily accepted by surgeons outside the United States, i.e., in Asia and Europe.

In addition to silicon nitride, we also sell metal-based products in the United States that provide surgeons and hospitals with a complete package for spinal surgery. These metal products are designed to address spinal deformity and degenerative conditions. Although these metal products have accounted for approximately 34.8% and 37.2% of our product revenues for the quarterly periods ended September 30, 2016 and September 30, 2015, respectively, and 48% and 52% of our product revenues for the years ended December 31, 2015 and 2014, respectively, we remain focused on developing and promoting silicon nitride, and driving its adoption through a scientifically-intense, data-driven strategy.

In addition to direct sales, we have targeted original equipment manufacturer (“OEM”) and private label partnerships in order to accelerate adoption of silicon nitride, both in the spinal space, and also in future markets such as hip and knee replacements, dental, extremities, trauma, and sports medicine. Existing biomaterials, based on plastics, metals, and bone grafts have well-recognized limitations that we believe are addressed by silicon nitride, and we are uniquely positioned to convert existing, successful implant designs made by other companies into silicon nitride. We believe OEM and private label partnerships will allow us to work with a variety of partners, accelerate the adoption of silicon nitride, and realize incremental revenue at improved operating margins, when compared to the cost-intensive direct sales model.

We believe that silicon nitride addresses many of the biomaterial-related limitations in fields such as hip and knee replacements, dental implants, sports medicine, extremities, and trauma surgery. We further believe that the inherent material properties of silicon nitride, and the ability to formulate the material in a variety of compositions, combined with precise control of the surface properties of the material, opens up a number of commercial opportunities across orthopedic surgery, neurological surgery, maxillofacial surgery, and other medical disciplines.

We operate a 30,000 square foot manufacturing facility at our corporate headquarters in Salt Lake City, Utah, and we believe we are the only vertically integrated silicon nitride medical device manufacturer in the world.

## **Corporate Information**

We were incorporated in Delaware in 1996 under the name Amedica Corp. and have since changed our name to Amedica Corporation. In September 2010, we acquired all of the outstanding shares of US Spine, Inc. which then became our wholly owned subsidiary, which is our only subsidiary. Our principal executive offices are located at 1885 West 2100 South, Salt Lake City, Utah 84119, and our telephone number is (801) 839-3500. Our website address is [www.amedica.com](http://www.amedica.com). The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

## **The Offering**

The selling stockholders named in this prospectus may offer and sell up to 962,380 shares of our common stock. Our common stock is currently listed on The NASDAQ Capital Market under the symbol "AMDA." Shares of common stock that may be offered in this offering, when issued and paid for, will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling stockholders of any of the common stock covered by this prospectus. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to the shares of common stock that have been issued pursuant to the settlement agreement in the private placement described below. Throughout this prospectus, when we refer to the selling stockholders, we are referring to the selling stockholders named herein and, as applicable, any donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

## **Selling Stockholders**

Effective November 9, 2016, we entered into a settlement and release agreement (the "Settlement Agreement"), with each of the selling stockholders named in this prospectus in full settlement of a lawsuit filed against us on April 1, 2016 by Hampshire MedTech Partners II, GP ("Hampshire GP"), on behalf of itself and the other selling stockholders, in the Travis County, Texas 200th Judicial District Court relating to a Warrant to Purchase Shares of Common Stock issued by us to Hampshire MedTech Partners II, LP. In connection with the Settlement Agreement we issued a total of 962,380 shares of our common stock to the selling stockholders. Pursuant to the Settlement Agreement, we agreed to file the registration statement of which this prospectus is a part with the Securities and Exchange Commission (the "SEC), to register the sale or other disposition of the shares of our common stock we issued and to use our best efforts

to cause the Securities and Exchange Commission to declare the registration statement effective.

## **RISK FACTORS**

An investment in our securities involves a high degree of risk. You should carefully read and consider the risks described below, as well as the other information in this prospectus and other information incorporated by reference herein, before deciding to invest in our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations or cash flows. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment.

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

**We have incurred net losses since our inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We may never achieve or sustain profitability.**

We have incurred substantial net losses since our inception. For the years ended December 31, 2015 and 2014 we incurred a net loss of \$23.9 million and \$32.6 million, respectively, and used cash in operations of \$9.1 million and \$14.5 million, respectively. We have an accumulated deficit of \$209.3 million at September 30, 2016. Our losses have resulted principally from costs incurred in connection with our sales and marketing activities, research and development activities, manufacturing activities, general and administrative expenses associated with our operations, impairments on intangible assets, interest expense, loss on extinguishment of debt and offering costs. Even if we are successful in launching additional products into the market, we expect to continue to incur substantial losses for the foreseeable future as we continue to sell and market our current products and research and develop, and seek regulatory approvals for, our product candidates.

If sales revenue from any of our current products or product candidates that receive marketing clearance from the FDA or other regulatory body is insufficient, if we are unable to develop and commercialize any of our product candidates, or if our product development is delayed, we may never become profitable. Even if we do become profitable, we may be unable to sustain or increase our profitability on a quarterly or annual basis.

**Our success depends on our ability to successfully commercialize silicon nitride-based medical devices, which to date have experienced only limited market acceptance.**

We believe we are the first and only company to use silicon nitride in medical applications. To date, however, we have had limited acceptance of our silicon nitride-based products and our product revenue has been derived substantially from our non-silicon nitride products. In order to succeed in our goal of becoming a leading biomaterial technology company utilizing silicon nitride, we must increase market awareness of our silicon nitride interbody spinal fusion products, continue to implement our sales and marketing strategy, enhance our commercial infrastructure and commercialize our silicon nitride joint replacement components and other products. If we fail in any of these endeavors or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

**Our current products and our future products may not be accepted by hospitals and surgeons and may not become commercially successful.**

Although we received 510(k) regulatory clearance from the FDA for our first silicon nitride spinal fusion products in 2008, we have not been able to obtain significant market share of the interbody spinal fusion market to date, and may not obtain such market share in the future. Even if we receive regulatory clearances or approvals for our product candidates in development, these product candidates may not gain market acceptance among orthopedic surgeons and the medical community. Orthopedic surgeons may elect not to use our products for a variety of reasons, including:

lack or perceived lack of evidence supporting the beneficial characteristics of our silicon nitride technology;

limited long-term data on the use of silicon nitride in medical devices;

lower than expected clinical benefits in comparison with other products;

the perception by surgeons that there are insufficient advantages of our products relative to currently available products;

hospitals may choose not to purchase our products;

group purchasing organizations may choose not to contract for our products, thus limiting availability of our products to hospital purchasers;

the price of our products, which may be higher than products made of the other commonly used biomaterials in the interbody spinal fusion market and total joint market;

lack of coverage or adequate payment from managed care plans and other third-party payers for the procedures that use our products;

Medicare, Medicaid or other third-party payers may limit or not permit reimbursement for procedures using our products;

ineffective marketing and distribution support;

the time and resources that may be required for training, or the inadequate training, of surgeons in the proper use of our products;

the development of alternative biomaterials and products that render our products less competitive or obsolete; and

the development of or improvement of competitive products.

**If surgeons do not perceive our silicon nitride products and product candidates as superior alternatives to competing products, we will not be able to generate significant revenues, if any.**

Even if surgeons are convinced of the superior characteristics of our silicon nitride products and our product candidates that we successfully introduce compared to the limitations of the current commonly used biomaterials, surgeons may find other methods or turn to other biomaterials besides silicon nitride to overcome such limitations. For instance, with respect to interbody spinal fusion products, surgeons or device manufacturers may use more effective markers for enhancing the imaging compatibility of PEEK devices, more effective antibiotics to prevent or treat implant-related infections, and more effective osteoconductive and osteoinductive materials when implanting an interbody spinal fusion device. Device manufacturers may also coat metal with existing traditional ceramics to reduce the risk of metal wear particles and corrosion in total joint replacement implants. Additionally, surgeons may increase their use of metal interbody spinal fusion devices if there is an increasing perception that PEEK devices are limited by their strength and resistance to fracture.

**If we are unable to increase the productivity of our sales and marketing infrastructure we will not be able to penetrate the spinal fusion market.**

We market and sell our products to surgeons and hospitals in the United States and select markets in Europe and South America using a network of independent third-party distributors who have existing surgeon relationships. We manage this distribution network through our in-house sales and marketing management team. We may also establish distribution collaborations in the United States and abroad in instances where access to a large or well-established sales and marketing organization may help to expand the market or accelerate penetration for selected products.

We cannot assure you that we will succeed in entering into and maintaining productive arrangements with an adequate number of distributors that are sufficiently committed to selling our products. The establishment of a distribution network is expensive and time consuming. As we launch new products and increase our marketing effort with respect to existing products, we will need to continue to hire, train, retain and motivate skilled independent distributors with significant technical knowledge in various areas, such as spinal fusion and total hip and knee joint replacement. In addition, the commissions we pay our distributors have increased over time, which has resulted in higher sales and marketing expenses, and those commissions and expenses may increase in the future. Furthermore, current and potential distributors may market and sell the products of our competitors. Even if the distributors market and sell our products, our competitors may be able, by offering higher commission payments or other incentives, to persuade these distributors to reduce or terminate their sales and marketing efforts related to our products. The distributors may also help competitors solicit business from our existing customers. Some of our independent distributors account for a significant portion of our sales volume, and, if we were to lose them, our sales could be adversely affected.

Even if we engage and maintain suitable relationships with an adequate number of distributors, they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our products. We have been unable to obtain meaningful market share in the interbody spinal fusion device market with our current silicon nitride products to date and we may not be successful in increasing the productivity of our sales and marketing team and distribution network to gain meaningful market share for our silicon nitride products, which could adversely affect our business and financial condition.

**The orthopedic market is highly competitive and we may not be able to compete effectively against the larger, well-established companies that dominate this market or emerging and small innovative companies that may seek to obtain or increase their share of the market.**

The markets for spinal fusions and total hip and knee implant products are intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Medtronic, Inc.; DePuy Synthes Companies, a group of Johnson & Johnson companies; Stryker Corporation; Biomet, Inc.; Zimmer Holdings, Inc.; and Smith & Nephew plc, account for a significant amount of orthopedic sales



worldwide.

These companies enjoy significant competitive advantages over us, including:

broad product offerings, which address the needs of orthopedic surgeons and hospitals in a wide range of procedures;

products that are supported by long-term clinical data;

greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;

existing relationships with spine and joint reconstruction surgeons;

extensive intellectual property portfolios and greater resources for patent protection;

greater financial and other resources for product research and development;

greater experience in obtaining and maintaining FDA and other regulatory clearances and approvals for products and product enhancements;

established manufacturing operations and contract manufacturing relationships;

significantly greater name recognition and widely recognized trademarks; and

established relationships with healthcare providers and payers.

Our products and any product candidates that we may introduce into the market may not enable us to overcome the competitive advantages of these large and dominant orthopedic companies. In addition, even if we successfully introduce additional product candidates incorporating our silicon nitride biomaterial into the market, emerging and small innovative companies may seek to increase their market share and they may eventually possess competitive advantages, which could adversely impact our business. Our competitors may also employ pricing strategies that could adversely affect the pricing of our products and pricing in the spinal fusion and total joint replacement market generally.

Moreover, many other companies are seeking to develop new biomaterials and products which may compete effectively against our products in terms of performance and price. For example, Smith & Nephew has developed a ceramic-coated metal, known as Oxinium, which may overcome certain of the limitations of metal joint replacement products and could directly compete with our silicon nitride and silicon nitride-coated product candidates.

**We have significant customer concentration, so that economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results.**

A small number of customers account for a substantial portion of our product revenues. Our customers are primarily hospitals and surgical centers. At December 31, 2015 and 2014, our largest customer, Bon Secours St. Mary's Hospital, or St. Mary's, had a receivable balance of approximately 7% and 9%, respectively, of our total trade accounts receivable. In addition, St. Mary's accounted for 12% and 18% of our product revenues for each of the years ended December 31, 2015 and 2014. Sales of our products to our customers, including St. Mary's, are not based on long-term, committed-volume purchase contracts, and we may not continue to receive significant revenues from St. Mary's or any customer. Because of our significant customer concentration, our revenue could fluctuate significantly due to changes in economic conditions, the use of competitive products, or the loss of, reduction of business with, or less favorable terms with St. Mary's or any of our other significant customers. A significant portion of St. Mary's' purchases have been of our non-silicon nitride products, so it may be able to purchase competitive similar products from others. A reduction or delay in orders from St. Mary's or any of our other significant customers, or a delay or default in payment by any significant customer, could materially harm our business and results of operations.

**The manufacturing process for our silicon nitride products is complex and requires sophisticated state-of-the-art equipment, experienced manufacturing personnel and highly specialized knowledge. If we are unable to manufacture our silicon nitride products on a timely basis consistent with our quality standards, our results of operation will be adversely impacted.**

In order to control the quality, cost and availability of our silicon nitride products, we developed our own manufacturing capabilities. We operate a 30,000 square foot manufacturing facility which is certified under the ISO 13485 medical device manufacturing standard for medical devices and operates under the FDA's quality systems regulations, or QSRs. All operations with the exceptions of raw material production, cleaning, packaging and sterilization are performed at this facility.

In order to mitigate the risk associated with us being the sole manufacturer of our silicon nitride medical device products, in June 2014, we entered into a manufacturing development and supply agreement with Kyocera Industrial Ceramics Corporation, or Kyocera. We updated our material master file and submitted a 510(k) with the FDA in the third quarter of 2014 to qualify Kyocera as a second source supplier of our silicon nitride products. Kyocera has been qualified as a second source supplier of our silicon nitride products. Although we expect this arrangement with Kyocera to continue, if Kyocera ceases to continue as a qualified manufacturer of these products and product

candidates, we will be the sole manufacturer of these products and will need to seek other potential secondary manufacturers. Our reliance solely on our internal resources to manufacture our silicon nitride products entails risks to which we would not be subject if we had secondary suppliers for their manufacture, including:

the inability to meet our product specifications and quality requirements consistently;

a delay or inability to procure or expand sufficient manufacturing capacity to meet additional demand for our products;

manufacturing and product quality issues related to the scale-up of manufacturing;

the inability to produce a sufficient supply of our products to meet product demands;

the disruption of our manufacturing facility due to equipment failure, natural disaster or failure to retain key personnel; and

our inability to ensure our compliance with regulations and standards of the FDA, including QSRs, and corresponding state and international regulatory authorities, including the CFDA.

Any of these events could lead to a reduction in our product sales, product launch delays, failure to obtain regulatory clearance or approval or impact our ability to successfully sell our products and commercialize our products candidates.

**We depend on a limited number of third-party suppliers for key raw materials used in the manufacturing of our silicon nitride products, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.**

We rely on a limited number of third-party suppliers for the raw materials required for the production of our silicon nitride products and product candidates. Our dependence on a limited number of third-party suppliers involves several risks, including limited control over pricing, availability, quality, and delivery schedules for raw materials. We have no supply agreements in place with any of our suppliers and cannot be certain that our current suppliers will continue to provide us with the quantities of raw materials that we require or that satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or single sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel within a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the production of our silicon nitride products and product candidates and delay the development and commercialization of our product candidates, including limiting supplies necessary for commercial sale, clinical trials and regulatory approvals, which could have a material adverse effect on our business.

**Use of third-party manufacturers increases the risk that we will not have adequate supplies of our non-silicon nitride products or instrumentation sets.**

The majority of our product revenue is currently generated by sales of non-silicon nitride products. Our reliance on a limited number of third-party manufacturers to supply us with our non-silicon nitride products and instruments exposes us to risks that could delay our sales, or result in higher costs or lost product revenues. In particular, our manufacturers could:

encounter difficulties in achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of our commercially available non-silicon nitride products to meet market demand for those products, or they could experience similar problems that result in the manufacture of insufficient quantities of our non-silicon nitride product candidates; and

fail to follow and remain in compliance with the FDA-mandated QSRs, compliance which is required for all medical devices, or fail to document their compliance to QSRs, either of which could lead to significant delays in the availability of materials for our non-silicon nitride products or instrumentation sets.

If we are unable to obtain adequate supplies of our non-silicon nitride products and related instrumentation sets that meet our specifications and quality standards, it will be difficult for us to compete effectively. We have no supply agreements in place with our manufacturers and they may change the terms of our future orders or choose not to supply us with products or instrumentation sets in the future. Furthermore, if a third-party manufacturer from whom we purchase fails to perform its obligations, we may be forced to purchase products or related instrumentation from other third-party manufacturers, which we may not be able to do on reasonable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the re-verification of an existing manufacturer could negatively affect our ability to produce and distribute our non-silicon nitride products or instruments in a timely manner.

**In order to be successful, we must expand our available product lines of silicon nitride-based medical devices by commercializing new product candidates, but we may not be able to do so in a timely fashion and at expected costs, or at all.**

Although we are currently marketing our silicon nitride interbody spinal fusion implants, in order to be successful, we will need to expand our product lines to include other silicon nitride devices. Therefore, we are developing silicon nitride product candidates for total hip and knee replacement procedures and are exploring the application of our silicon nitride technology for other potential applications. However, we have yet to commercialize any silicon nitride products beyond our spinal fusion products. To succeed in our commercialization efforts, we must effectively continue product development and testing, obtain regulatory clearances and approvals, and enhance our sales and

marketing capabilities. We may also have to write down significant inventory if existing products are replaced by new products. Because of these uncertainties, there is no assurance that we will succeed in bringing any of our current or future product candidates to market. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

**We will depend on one or more strategic partners to develop and commercialize our total joint replacement product candidates, and if our strategic partners are unable to execute effectively on our agreements with them, we may never become profitable.**

We are seeking a strategic partner to develop and commercialize our total joint replacement product candidates. We will be reliant on our strategic partners to develop and commercialize a total hip or knee joint replacement product candidate that utilizes silicon nitride-coated components, although we have not yet entered into an agreement with any strategic partner to develop products with these silicon nitride-coated components and may be unable to do so on agreeable terms. In order to succeed in our joint commercialization efforts, we and any future partners must execute effectively on all elements of a combined business plan, including continuing to establish sales and marketing capabilities, manage certified, validated and effective commercial-scale manufacturing operations, conduct product development and testing, and obtain regulatory clearances and approvals for our product candidate. If we or any of our strategic partners fail in any of these endeavors, or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

**Part of our strategy is to establish and develop OEM partnerships and arrangements, which subjects us to various risks.**

Because we believe silicon nitride is a superior platform and technology for application in the spine, total joint and other markets, we are establishing OEM partnerships with other companies to replace their materials and products with silicon nitride. Sales of products to OEM customers will expose our business to a number of risks. Sales through OEM partners could be less profitable than direct sales. Sales of our products through multiple channels could also confuse customers and cause the sale of our products to decline. In addition, OEM customers will require that products meet strict standards. Our compliance with these requirements could result in increased development, manufacturing, warranty and administrative costs. A significant increase in these costs could adversely affect our operating results. If we fail to meet OEM specifications on a timely basis, our relationships with our OEM partners may be harmed. Furthermore, we would not control our OEM partners, and they could sell competing products, may not incorporate our technology into their products in a timely manner and may devote insufficient sales efforts to the OEM products.

**If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, it is unlikely our products will be widely used.**

In the United States, the commercial success of our existing products and any future products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for procedures utilizing our products. Because we typically receive payment directly from hospitals and surgical centers, we do not anticipate relying directly on payment from third-party payers for our products. However, hospitals and other healthcare providers that purchase our orthopedic products for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a “bundled” rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. A Medicare national or local coverage decision denying coverage for one or more of our products could result in private and other third-party payers also denying coverage for our products. Third-party payers also may deny reimbursement for our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payer, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payers underscore the

uncertainty that our products face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to group purchasing organizations, which typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices. Such contracts often include exceptions for purchasing certain innovative new technologies, however. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product “off contract.”

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payers frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payers are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. As a result of these programs, and related payer efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our implants profitably if third-party payers deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payers to hospitals could adversely impact our ability to market and sell our products and negatively affect our financial performance.

In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost-effective by international third-party payers, that reimbursement will be available or, if available, that the third-party payers’ reimbursement policies will not adversely affect our ability to sell our products profitably. Any failure to receive regulatory or reimbursement approvals would negatively impact market acceptance of our products in any international markets in which those approvals are sought.

**Prolonged negative economic conditions in domestic and international markets may adversely affect us, our suppliers, partners and consumers, and the global orthopedic market which could harm our financial position.**

Global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and availability of credit, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Credit and financial markets and confidence in economic conditions might deteriorate further. Our business may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. In addition, there is a risk that one or more of our current suppliers may not continue to operate. Any lender that is obligated to provide funding to us under any future credit agreement with us may not be able to provide funding in a timely manner, or at all, when we require it. The cost of, or lack of, available credit or equity financing could impact our ability to develop sufficient liquidity to maintain or grow our company. These negative changes in domestic and international economic conditions or additional disruptions of either or both of the financial and credit markets may also affect third-party payers and may have a material adverse effect on our business, results of operations, financial condition and liquidity.

In addition, we believe that various demographics and industry-specific trends will help drive growth in the orthopedics markets, but these demographics and trends are uncertain. Actual demand for orthopedic products generally, and our products in particular, could be significantly less than expected if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments gain widespread acceptance.

**We are dependent on our senior management team, engineering team, sales and marketing team and surgeon advisors, and the loss of any of them could harm our business.**

The members of our current senior management team have worked together in their new positions with us for a limited time and may not be able to successfully implement our strategy. In addition, we have not entered into employment agreements, other than change-in-control severance agreements, with any of the members of our senior management team. There are no assurances that the services of any of these individuals will be available to us for any specified period of time. The successful integration of our senior management team, the loss of members of our senior management team, sales and marketing team, engineering team and key surgeon advisors, or our inability to attract or retain other qualified personnel or advisors could have a material adverse effect on our business, financial condition and results of operations.

**If we experience significant disruptions in our information technology systems, our business, results of operations and financial condition could be adversely affected.**



The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage our sales and marketing, accounting and financial functions; manufacturing processes; inventory; engineering and product development functions; and our research and development functions. As such, our information technology systems are vulnerable to damage or interruption including from earthquakes, fires, floods and other natural disasters; terrorist attacks and attacks by computer viruses or hackers; power losses; and computer systems, or Internet, telecommunications or data network failures. The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

### **Risks Related to Our Capital Resources and Impairments**

**We will require additional financing and our failure to obtain additional funding would force us to delay, reduce or eliminate our product development programs or commercialization efforts.**

We currently have limited committed sources of capital and we have limited liquidity. Our cash and cash equivalents as of September 30, 2016 was \$10.6 million. We require substantial future capital in order to continue to conduct the research and development and regulatory clearance and approval activities necessary to bring our products to market, to establish effective marketing and sales capabilities. Our existing capital resources are not sufficient to enable us to fund the completion of the development and commercialization of all of our product candidates. We cannot determine with certainty the duration and completion costs of the current or future development and commercialization of our product candidates for spinal fusion procedures, joint replacement and coated metals or if, when, or to what extent we will generate revenues from the commercialization and sale of any of these product candidates for which we obtain regulatory approval. We may never succeed in achieving regulatory approval for certain or all of these product candidates. The duration, costs and timing of clinical trials and development of our spinal fusion, joint replacement and coated metal product candidates will depend on a variety of factors, including:

the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;

future clinical trial results we may must or choose to conduct;

potential changes in government regulation; and

the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of spinal fusion, joint replacement or coated metal product candidates could mean a significant change in the costs and timing associated with the development of these product candidates.

In addition, the repayment of the Hercules Loan and Security Agreement and the Hercules liquidity covenant limit our ability to use our cash and cash equivalents to fund our operations and may restrict our ability to continue development of our product candidates. Additionally, the Loan and Security Agreement with Hercules Technology restricts our ability to incur additional pari passu indebtedness, which may reduce our ability to seek additional financing. If adequate funds are not available on a timely basis, we may terminate or delay the development of one or more of our product candidates, or delay activities necessary to commercialize our product candidates. Additional funding may not be available to us on acceptable terms, or at all. Any additional equity financing, if available, may not be available on favorable terms and will most likely be dilutive to our current stockholders, and debt financing, if available, may involve more restrictive covenants. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations or could cause us to cease operations.

As a result of our debt obligations, we will need additional funds to meet our operational needs and capital requirements for product development, clinical trials and commercialization. The timing and amount of our future capital requirements will depend on many factors, including:

our ability to satisfy our obligation to pay principal and interest on the Loan and Security Agreement;

our ability to comply with the minimum liquidity covenant related to the Loan and Security Agreement;

the level of sales of our current products and the cost of revenue and sales and marketing;

the extent of any clinical trials that we will be required to conduct in support of the regulatory clearance of our total hip and knee replacement product candidates;

the scope, progress, results and cost of our product development efforts;

the costs, timing and outcomes of regulatory reviews of our product candidates;

the number and types of products we develop and commercialize;

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

the extent and scope of our general and administrative expenses.

**If we do not adhere to the financial covenants set forth in the Loan and Security Agreement with Hercules Technology, we will be in default of the Loan and Security Agreement.**

In June 2014 we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or Hercules Technology, as administrative and collateral agent for the lenders thereunder and as lender, and Hercules Technology III, LP, as lender. The Loan and Security Agreement provides us with a \$20 million term loan with a maturity date of January 1, 2018 and is secured by substantially all of our assets and is described in more detail in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report on Form 10-K.

The Loan and Security Agreement contains a minimum liquidity covenant that requires us to maintain cash and cash equivalents and availability under the Loan and Security Agreement of not less than an amount that varies based on the loan amount and reduces as the loan amount is reduced with a maximum cash requirement of \$9.0 million if the loan amount exceeds \$19.0 million and a potential minimum cash requirement of \$2.5 million if the loan amount is \$7.0 million or less. As of September 30, 2016, the minimum liquidity covenant was \$3.5 million. We anticipate we will need to refinance the Loan and Security Agreement or obtain additional funding in the second quarter of 2017 to maintain compliance with the minimum liquidity covenant through the next twelve months. Furthermore, if we are unable to access additional funds prior to becoming non-compliant with the liquidity covenant, the entire remaining balance of the Loan and Security Agreement could become immediately due and payable at the option of Hercules Technology.

Hercules Technology could declare a default under the Loan and Security Agreement upon the occurrence of a material adverse effect, as defined under the credit facility, thereby requiring us to either repay the outstanding indebtedness immediately or attempt to reverse the declaration of default through negotiation or litigation. Any declaration of an event of default would significantly harm our business and prospectus and could cause the price of our common stock to decline.

**Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.**

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

**Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future.**

Our report from our independent registered public accounting firm for the year ended December 31, 2015 includes an explanatory paragraph stating that our recurring losses from operations and our need to obtain additional financing in order to satisfy our debt obligations and to be compliant with covenants under our debt obligations through 2016 raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient additional funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

**An impairment charge could have a material adverse effect on our financial condition and results of operations.**

We are required to test acquired goodwill for impairment on an annual basis. Goodwill represents the excess of the amount paid over the fair value of the net assets at the date of the acquisition. We have chosen to complete our annual impairment reviews of goodwill at the end of each calendar year. We also are required to test goodwill for impairment between annual tests if events occur or circumstances change that would more likely than not reduce our enterprise fair value below its book value. In addition, we are required to test our finite-lived intangible assets for impairment if events occur or circumstances change that would indicate the remaining net book value of the finite-lived intangible assets might not be recoverable. These events or circumstances could include a significant change in the business climate, including a significant sustained decline in our market value, legal factors, operating performance indicators, competition, sale or disposition of a significant portion of our business and other factors.

If the fair market value of our reporting unit is less than its book value, we could be required to record an impairment charge. The valuation of a reporting unit requires judgment in estimating future cash flows, discount rates and other factors. In making these judgments, we evaluate the financial health of our business, including such factors as industry performance, changes in technology and operating cash flows. Changes in our forecasts or decreases in the value of our common stock could cause book values of our reporting unit to exceed its fair value, which may result in goodwill impairment charges. The amount of any impairment could be significant and could have a material adverse effect on our reported financial results for the period in which the charge is taken.

### **Risks Related to Regulatory Approval of Our Products and Other Government Regulations**

**Our long-term success depends substantially on our ability to obtain regulatory clearance or approval and thereafter commercialize our product candidates; we cannot be certain that we will be able to do so in a timely manner or at all.**

The process of obtaining regulatory clearances or approvals to market a medical device from the FDA or similar regulatory authorities outside of the United States can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, or at all. The FDA's 510(k) clearance process generally takes one to six months from the date of submission, depending on whether a special or traditional 510(k) premarket notification has been submitted, but can take significantly longer. An application for premarket approval, or PMA, must be submitted to the FDA if the device cannot be cleared through the 510(k) clearance process or is not exempt from premarket review by the FDA. The PMA process almost always requires one or more clinical trials and can take two to three years from the date of filing, or even longer. In some cases, including in the case of our interbody spinal fusion devices which incorporate our CSC technology and our solid silicon nitride femoral head component, the FDA requires clinical data as part of the 510(k) clearance process.

It is possible that the FDA could raise questions about our spinal fusion products, our spinal fusion product candidates and our total hip and knee joint replacement product candidates and could require us to perform additional studies on our products and product candidates. Even if the FDA permits us to use the 510(k) clearance process, we cannot assure you that the FDA will not require either supporting data from laboratory tests or studies that we have not conducted, or substantial supporting clinical data. If we are unable to use the 510(k) clearance process for any of our product candidates, are required to provide clinical data or laboratory data that we do not possess to support our 510(k) premarket notifications for any of these product candidates, or otherwise experience delays in obtaining or fail to obtain regulatory clearances, the commercialization of our product candidates in the United States will be delayed or prevented, which will adversely affect our ability to generate additional revenues. It also may result in the loss of potential competitive advantages that we might otherwise attain by bringing our products to market earlier than our competitors. Additionally, although the FDA allows modifications to be made to devices that have received 510(k) clearance with supporting documentation, the FDA may disagree with our decision to modify our cleared devices without submission of a new 510(k) premarket notification, subjecting us to potential product recall, field alerts and corrective actions. Any of these contingencies could adversely affect our business.

Similar to our compliance with U.S. regulatory requirements, we must obtain and comply with international requirements, including those of the CFDA, in order to market and sell our products outside of the United States and we may only promote and market our products, if approved, as permitted by applicable regulatory authorities. There is no guarantee that we will receive the necessary regulatory approvals for our product candidates either inside the United States or internationally, including approvals from the CFDA. If our product candidates do not receive necessary regulatory approvals, our business could be materially and adversely affected.

**The safety of our products is not yet supported by long-term clinical data, and they may prove to be less safe and effective than our laboratory data indicate.**

We obtained FDA clearance for each of our products that we currently market, and we have sought and intend to seek FDA clearance or approval through the FDA's 510(k) or PMA process and, where applicable, CE marking for our product candidates. The 510(k) clearance process is based on the FDA's agreement that a new product candidate is substantially equivalent to an already marketed product for which a PMA was not required. While most 510(k) premarket notifications do not require clinical data for clearance, the FDA may request that such data be provided. Long-term clinical data or marketing experience obtained after clearance may indicate that our products cause unexpected complications or other unforeseen negative effects. If this happens, we could be subject to the withdrawal of our marketing clearance and other enforcement sanctions by the FDA or other regulatory authority, product recalls, significant legal liability, significant negative publicity, damage to our reputation and a dramatic reduction in our ability to sell our products, any one of which would have a material adverse effect on our business, financial condition and results of operations.

**We expect to be required to conduct clinical trials to support regulatory approval of some of our product candidates. We have little experience conducting clinical trials, they may proceed more slowly than anticipated, and we cannot be certain that our product candidates will be shown to be safe and effective for human use.**

In order to commercialize our product candidates in the United States, we must submit a PMA for some of these product candidates, which will require us to conduct clinical trials. We also plan to provide the FDA with clinical trial data to support some of our 510(k) premarket notifications. We will receive approval or clearance from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, through well-designed and properly conducted clinical trials, that our product candidates are safe and effective and otherwise meet the appropriate standards required for approval or clearance for specified indications.

Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Before we may begin clinical trials, we must submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. Because we do not have the experience or the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay the completion of our clinical trials in the future and negatively impact our ability to obtain FDA approval for, and to introduce our product candidates:

failure to obtain financing necessary to bear the cost of designing and conducting clinical trials;

failure to obtain approval from the FDA or foreign regulatory authorities to commence investigational studies;

conditions imposed on us by the FDA or foreign regulatory authorities regarding the scope or design of our clinical trials;

failure to find a qualified CRO to conduct our clinical trials or to negotiate a CRO services agreement on favorable terms;

delays in obtaining or in our maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

insufficient supply of our product candidates or other materials necessary to conduct our clinical trials;

difficulties in enrolling patients in our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;

failure on the part of the CRO to conduct the clinical trial in accordance with regulatory requirements;

our failure to maintain a successful relationship with the CRO or termination of our contractual relationship with the CRO before completion of the clinical trials;

serious or unexpected side effects experienced by patients in whom our product candidates are implanted; or

failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

Our clinical trials may need to be redesigned or may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidates, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

**Our current and future relationships with third-party payers and current and potential customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm administrative burdens and diminished profits and future earnings.**



Our current and future arrangements with third-party payers and current and potential customers, including providers and physicians, as well as PODs, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In addition, we may be subject to transparency laws and patient privacy regulations by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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 obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the Physician Payments Sunshine Act, which requires (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, with data collection beginning on August 1, 2013, (ii) applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held in such entities by physicians and their immediate family members, with data collection beginning on August 1, 2013, (iii) manufacturers to submit reports to CMS by March 31, 2014 and the 90th day of each subsequent calendar year, and (iv) disclosure of such information by CMS on a publicly available website beginning in September 2014; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

**Recently enacted and future legislation may increase the difficulty and cost for us to obtain and monitor regulatory approval or clearance of our product candidates and affect the prices we may obtain for our products.**

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay clearance and/or approval of our product candidates, restrict or regulate post-clearance and post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain marketing approval or clearance.

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 regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, results of operations and financial condition. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

Among policy makers and payers 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 and expanding access. In

the United States, the medical device industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our products and product candidates are:

a 2.3% medical device excise tax on the U.S. sales of most medical devices, for which a moratorium on the payment of the excise tax for 2016 and 2017 was enacted in December 2015;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, and new government investigative powers and enhanced penalties for non-compliance;

new requirements under the federal Open Payments program and its implementing regulations;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

creation of an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction 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 aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 1, 2013, the President signed an executive order implementing the Budget Control Act's 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations.

We expect that the ACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may affect our ability to generate revenue and profits or commercialize our product candidates.

In the European Union and some other international markets, the government provides health care at a low cost to consumers and regulates prices of healthcare products, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries are reducing their public expenditures and we expect to see strong efforts to reduce healthcare costs in international markets, including patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates and recoveries of past price increases. These cost control measures could reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third-party cross border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

### **Risks Related to Our Intellectual Property and Litigation**

**If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to commercialize our orthopedic products successfully will be harmed, and we may not be able to operate our business profitably.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies incorporated in our products. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO, or foreign patent offices. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO or foreign patent offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO or foreign patent offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.

Our competitors may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may issue in the future, which could prevent or limit our ability to market our products and could limit our ability to stop competitors from marketing products that are substantially equivalent to ours. In addition, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but that are not covered by our patents.

We have also entered into confidentiality and assignment of intellectual property agreements with all of our employees, consultants and advisors as one of the ways we seek to protect our intellectual property and other proprietary technology. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management's attention from managing our business. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

**We have no patent protection covering the composition of matter for our solid silicon nitride or the process we use for manufacturing our solid silicon nitride, and competitors may create silicon nitride formulations substantially similar to ours.**

Although we have a number of U.S. and foreign patents and pending applications relating to our solid silicon nitride products or product candidates, we have no patent protection either for the composition of matter for our silicon nitride or for the processes of manufacturing solid silicon nitride. As a result, competitors may create silicon nitride formulations substantially similar to ours, and use their formulations in products that may compete with our silicon nitride products, provided they do not violate our issued product patents. Although we have, and will continue to develop, significant know-how related to these processes, there can be no assurance that we will be able to maintain this know-how as trade secrets, and competitors may develop or acquire equally valuable or more valuable know-how related to the manufacture of silicon nitride.

**We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from marketing our commercially available products or product candidates and/or reduce the margins we may realize from our products that we may commercialize.**

The medical devices industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the orthopedic market increases and as we achieve more visibility in the market place and introduce products to market.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we were found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful, and royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products that incorporate them, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, all of which would have a material adverse effect on our business, financial condition and results of operations.

In addition, in order to further our product development efforts, we have entered into agreements with orthopedic surgeons to help us design and develop new products, and we expect to enter into similar agreements in the future. In certain instances, we have agreed to pay such surgeons royalties on sales of products which incorporate their product development contributions. There can be no assurance that surgeons with whom we have entered into such arrangements will not claim to be entitled to a royalty even if we do not believe that such products were developed by cooperative involvement between us and such surgeons. In addition, some of our surgeon advisors are employed by academic or medical institutions or have agreements with other orthopedic companies pursuant to which they have agreed to assign or are under an obligation to assign to those other companies or institutions their rights in inventions which they conceive or develop, or help conceive or develop.

There can be no assurance that one or more of these orthopedic companies or institutions will not claim ownership rights to an invention we develop in collaboration with our surgeon advisors or consultants on the basis that an agreement with such orthopedic company or institution gives it ownership rights in the invention or that our surgeon advisors or consultants otherwise have an obligation to assign such inventions to such company or institution. Any such claim against us, even without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

**We may be subject to damages resulting from claims that we, our employees, or our independent sales agencies have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition agreements with our competitors or non-solicitation agreements.**

Many of our employees were previously employed at other orthopedic companies, including our competitors and potential competitors. Many of our distributors and potential distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that either we, or these employees or distributors, have inadvertently or otherwise used or disclosed the trade secrets or other proprietary information of our competitors. In addition, we have been and may in the future be subject to claims that we caused an employee or sales agent to break the terms of his or her non-competition agreement or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize products, which could have an adverse effect on our business, financial condition and results of operations.

**If our silicon nitride products or our product candidates conflict with the rights of others, we may not be able to manufacture or market our products or product candidates, which could have a material and adverse effect on us.**

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Issued patents held by others may limit our ability to develop commercial products. All issued patents are entitled to a presumption of validity under the laws of the United States. If we need suitable licenses to such patents to permit us to develop or market our product candidates, we may be required to pay significant fees or royalties and we cannot be certain that we would even be able to obtain such licenses. Competitors or third parties may obtain patents that may cover subject matter we use in developing the technology required to bring our products to market, that we use in producing our products, or that we use in treating patients with our products. We know that others have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If we were found to infringe any of these issued patents or any of the pending patent applications, when and if issued, we may be required to alter our processes or product candidates, pay licensing fees or cease activities. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us, in Europe, the United States and elsewhere, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Additionally, it is not possible to predict with certainty what patent claims may issue from pending applications. In the United States, for example, patent prosecution can proceed in secret prior to issuance of a patent, provided such application is not filed in foreign jurisdiction. For U.S. patent applications that are also filed in foreign jurisdictions, such patent applications will not publish until 18 months from the filing date of the application. As a result, third parties may be able to obtain patents with claims relating to our product candidates which they could attempt to assert against us. Further, as we develop our products, third parties may assert that we infringe the patents currently held or licensed by them, and we cannot predict the outcome of any such action.



There has been extensive litigation in the medical devices industry over patents and other proprietary rights. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license, grant cross-licenses and pay substantial royalties in order to continue to manufacture or market the affected products.

We cannot assure you that we would prevail in any legal action or that any license required under a third party patent would be made available on acceptable terms, or at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of claims of patent infringement or violation of other intellectual property rights, which could have a material and adverse effect on our business, financial condition and results of operations.

### **Risks Related to Potential Litigation from Operating Our Business**

**We may become subject to potential product liability claims, 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 design, testing, manufacture, sale and distribution of our currently marketed products and each of our product candidates that we are seeking to introduce to the market. The use of orthopedic medical devices can involve significant risks of serious complications, including bleeding, nerve injury, paralysis, infection, and even death. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. If longer-term patient results and experience indicate that our products or any component of a product causes tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management's attention from managing our business.

**Any claims relating to our improper handling, storage or disposal of biological or hazardous materials could be time consuming and costly.**

Although we do not believe that the manufacture of our silicon nitride or non-silicon nitride products will involve the use of hazardous materials, it is possible that regulatory authorities may disagree or that changes to our manufacturing processes may result in such use. Our business and facilities and those of our suppliers and future suppliers may therefore be subject to foreign, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations.

### **Risks Related to Our Common Stock**

**The price of our common stock is volatile and is likely to continue to fluctuate due to reasons beyond our control.**

The volatility of orthopedic company stocks, including shares of our common stock, often do not correlate to the operating performance of the companies represented by such stocks or our operating performance. Some of the factors that may cause the market price of our common stock to fluctuate include:

our ability to sell our current products and the cost of revenue;

our ability to develop, obtain regulatory clearances or approvals for, and market new and enhanced product candidates on a timely basis;

our ability to enter into OEM and private label partnership agreements and the terms of those agreements;

changes in governmental regulations or in the status of our regulatory approvals, clearances or future applications;

our announcements or our competitors' announcements regarding new products, product enhancements, significant contracts, number and productivity of distributors, number of hospitals and surgeons using products, acquisitions or strategic investments;

announcements of technological or medical innovations for the treatment of orthopedic pathology;

delays or other problems with the manufacturing of our products, product candidates and related instrumentation;

volume and timing of orders for our products and our product candidates, if and when commercialized;

changes in the availability of third-party reimbursement in the United States and other countries;

quarterly variations in our or our competitors' results of operations;

changes in earnings estimates or recommendations by securities analysts, if any, who cover our common stock;

failure to meet estimates or recommendations by securities analysts, if any, who cover our stock;

changes in the fair value of our derivative liabilities resulting from changes in the market price of our common stock, which may result in significant fluctuations in our quarterly and annual operating results;

changes in healthcare policy in the United States and internationally;

product liability claims or other litigation involving us;

sales of a substantial aggregate number of shares of our common stock;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

disputes or other developments with respect to intellectual property rights;

changes in accounting principles;

changes to tax policy; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent our stockholders from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit regardless of the merits of the case or the eventual outcome. Such a lawsuit also would divert the time and attention of our management from running our company.

**Securities analysts may not continue to provide coverage of our common stock or may issue negative reports, which may have a negative impact on the market price of our common stock.**

Since completing our initial public offering of shares of our common stock in February 2014, a limited number of securities analysts have begun providing research coverage of our common stock. If securities analysts do not continue to cover our common stock, the lack of research coverage may cause the market price of our common stock to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about our business. If one or more of the analysts who elect to cover us downgrade our stock, our stock price would likely decline rapidly. If one or more of these analysts cease coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and a global settlement among the Securities and Exchange Commission, or the SEC, other regulatory agencies and a number of investment banks, which was reached in 2003, many investment banking firms are required to contract with independent financial analysts for their stock research. It may be difficult for a company such as ours, with a smaller market capitalization, to attract independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

**Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.**

Our restated certificate of incorporation and restated bylaws contain provisions that could discourage, delay or prevent a merger, acquisition or other change in control of our company or changes in our board of directors that our stockholders might consider favorable, including transactions in which you might receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove management. These provisions:

allow the authorized number of directors to be changed only by resolution of our board of directors;

provide for a classified board of directors, such that not all members of our board will be elected at one time;

prohibit our stockholders from filling board vacancies, limit who may call stockholder meetings, and prohibit the taking of stockholder action by written consent;

prohibit our stockholders from making certain changes to our restated certificate of incorporation or restated bylaws except with the approval of holders of 75% of the outstanding shares of our capital stock entitled to vote;

require advance written notice of stockholder proposals that can be acted upon at stockholders meetings and of director nominations to our board of directors; and

authorize our board of directors to create and issue, without prior stockholder approval, preferred stock that may have rights senior to those of our common stock and that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. Any delay or prevention of a change in control transaction or changes in our board of directors could cause the market price of our common stock to decline.

**We do not intend to pay cash dividends.**

We have never declared or paid cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and any future earnings for debt service and use in the operation and expansion of our business. The Hercules Secured Credit Facility contains a negative covenant which prohibits us from paying dividends to our stockholders without the prior written consent of Hercules Technology. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends.

## Risks Related to Public Companies

**We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 and a “smaller reporting company” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Additionally, under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We are electing to delay such adoption of new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of this election, our financial statements may not be comparable to the financial statements of other public companies.

We may take advantage of these exemptions until we are no longer an emerging growth company. Under the JOBS Act, we may be able to maintain emerging growth company status for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 before the end of such five-year period or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31. Additionally, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

We are also currently a “smaller reporting company” as defined in the Securities Exchange Act of 1934, and in the event that we are still considered a smaller reporting company at such time as we cease being an emerging growth company, we will be required to provide additional disclosure in our SEC filings. However, similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting, and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of 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.

**If the bid price of our common stock price drops below \$1.00 for a period of 30 consecutive business days, our common stock may be subject to delisting from The NASDAQ Stock Market.**

On August 17, 2016, since the bid price of our common stock closed below the required minimum \$1.00 per share for 30 consecutive business days, NASDAQ notified us that our common stock may be subject to delisting. We were provided a grace period of 180-calendar days, or until February 13, 2017, to regain compliance with the minimum bid price requirement. If at any time during the 180-day grace period, the minimum closing bid price per share of our common stock closes at or above \$1.00 for a minimum of ten consecutive business days, we will regain compliance and the matter will be closed. In the event the Company does not regain compliance with Rule 5550(a)(2) within this compliance period, it may be eligible for additional time to regain compliance. To qualify for the additional time, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the minimum bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Nasdaq staff concludes that the Company will not be able to cure the deficiency, or if the Company determines not to submit the required materials or make the required representations, the Company's common stock will be subject to delisting by NASDAQ. If our common stock is delisted, it would adversely impact liquidity of our common stock and potentially result in lower bid prices for our common stock. There is no guarantee that our stock price will remain above \$1.00 per share or that it would recover after falling below that price.

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

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costly for us to obtain director and officer liability insurance for our directors and officers, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our board of directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other requirements related to being a public company, we may not be able to maintain the listing of our common stock on The NASDAQ Capital Market, which would likely have a material adverse effect on the trading price of our common stock.

## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to us. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

our ability to achieve sufficient market acceptance of any of our products or product candidates;

our ability to continue as a going concern due to our recurring losses from operations and our need to obtain additional financing to satisfy our debt obligations;

our ability to enter into and maintain successful OEM arrangements with third parties;

our perception of the growth in the size of the potential market for our products and product candidates;

our estimate of the advantages of our silicon nitride technology platform;

our ability to become a profitable biomaterial technology company;

our ability to comply with, or receive waivers from compliance with the covenants, made in the Hercules Secured Credit Facility;

our estimates regarding our needs for additional financing and our ability to obtain such additional financing on suitable terms;

our ability to succeed in obtaining FDA clearance or approvals for our product candidates;

our ability to receive CE Marks for our product candidates;

the timing, costs and other limitations involved in obtaining regulatory clearance or approval for any of our product candidates and product candidates and, thereafter, continued compliance with governmental regulation of our existing products and activities;

our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;

our ability to obtain sufficient quantities and satisfactory quality of raw materials to meet our manufacturing needs;

the availability of adequate coverage reimbursement from third-party payers in the United States;



our estimates regarding anticipated operating losses, future product revenue, expenses, capital requirements and liquidity;

our ability to maintain and continue to develop our sales and marketing infrastructure;

our ability to enter into and maintain suitable arrangements with an adequate number of distributors;

our manufacturing capacity to meet future demand;

our ability to establish Kyocera as a secondary manufacturing source for our silicon nitride products;

our ability to develop effective and cost efficient manufacturing processes for our products;

our reliance on third parties to supply us with raw materials and our non-silicon nitride products and instruments;

the safety and efficacy of products and product candidates;

the timing of and our ability to conduct clinical trials;

potential changes to the healthcare delivery systems and payment methods in the United States or internationally;

any potential requirement by regulatory agencies that we restructure our relationships with referring surgeons;

our ability to develop and maintain relationships with surgeons, hospitals and marketers of our products; and

our ability to attract and retain a qualified management team, engineering team, sales and marketing team, distribution team, design surgeons, surgeon advisors and other qualified personnel and advisors.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements.

Any forward-looking statement in this prospectus reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to publicly update or revise any forward-looking statements contained in this prospectus, whether as a result of new information, future events or otherwise.

## **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale or other disposition of shares of our common stock by the selling stockholders pursuant to this prospectus.

## **SELLING STOCKHOLDERS**

The shares of common stock being offered by the selling stockholders are those issued to the selling stockholders in the Settlement Agreement. For additional information regarding the Settlement Agreement, see “Prospectus Summary—Settlement Agreement” above. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time.

The table below lists the selling stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) of the shares of common stock held by each of the selling stockholders. The “*Shares of Common Stock Beneficially Owned Prior to Offering*” column lists the number of shares of common stock beneficially owned by the selling stockholders, based on their respective ownership of shares of common stock as of November 23, 2016.

The “*Number of Shares Being Offered*” column lists the shares of common stock being offered by this prospectus by the selling stockholders.

The “*Shares of Common Stock Beneficially Owned After Offering*” column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus. The selling stockholders may offer and sell all or part of the common stock covered by this prospectus, but no estimates can be made as to the number of shares of common stock that will be held by the selling stockholders after the completion of this offering.

The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares Being Offered	Shares of Common Stock Beneficially Owned After Offering	
	Number	Percent		Number	Percent
Security Holder					
Hampshire MedTech Partners II, GP, LLC (1)	9,623	*	9,623	—	*
Vestal Venture Capital GP (2)	481,191	1.8	481,191	—	*
Merrimac Investments, LLC (3)	96,238	*	96,238	—	*
Hampshire Asset Management, LLC (4)	86,614	*	86,614	—	*
Michael Brett Butler	96,238	*	96,238	—	*
William M. and Linda M. Swain as JTWROS	96,238	*	96,238	—	*
Transportation Insurance Agency, LLC (5)	48,119	*	48,119	—	*
Peter C. Dillingham as Trustee of the Peter C. Dillingham Trust (6)	48,119	*	48,119	—	*

\* Represents less than 1%.

- (1) Karl Kipke is the manager of Hampshire MedTech Partners II, GP, LLC. Accordingly, Mr. Kipke is the natural person with voting and dispositive power over these shares.
- (2) Al Lyons is the general partner of Vestal Venture Capital GP. Accordingly, Mr. Lyons is the natural person with voting and dispositive power over these shares.
- (3) Rob McLaughlin is the manager of Merrimac Investments, LLC. Accordingly, Mr. McLaughlin is the natural person with voting and dispositive power over these shares.
- (4) Karl Kipke is the manager of Hampshire Asset Management, LLC. Accordingly, Mr. Kipke is the natural person with voting and dispositive power over these shares.
- (5) Chad Dillingham is the manager of Transportation Insurance Agency, LLC. Accordingly, Mr. Dillingham is the natural person with voting and dispositive power over these shares.
- (6) Peter Dillingham is the trustee of the Peter C. Dillingham Trust. Accordingly, Mr. Dillingham is the natural person with voting and dispositive power over these shares.

Information about any other selling stockholders will be included in prospectus supplements or post-effective amendments, if required. Information about the selling stockholders may change from time to time. Any changed information with respect to which we are given notice will be included in prospectus supplements or, if required, in a post-effective amendment to the registration statement of which this prospectus is a part.

## **PLAN OF DISTRIBUTION**

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(7) or other applicable provision of the Securities Act supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(7) or other applicable provision of the Securities Act or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

## **LEGAL MATTERS**

The validity of the common stock being offered hereby was passed upon by Dorsey & Whitney LLP, Salt Lake City, Utah.

## **EXPERTS**

The consolidated financial statements of Amedica Corporation at December 31, 2015 and 2014, and for each of the two years in the period ended December 31, 2015, incorporated by reference herein have been audited by Mantyla McReynolds LLC, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the consolidated financial statements) incorporated by reference herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

This prospectus is part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and does not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. We maintain a website at [www.amedica.com](http://www.amedica.com). Information contained in or accessible through our website does not constitute a part of this prospectus.

## **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-33624):

our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed on March 23, 2016;

our Definitive Proxy Statement on Schedule 14A for our annual meeting of stockholders, filed with the SEC on April 12, 2016;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed on May 13, 2016;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 filed on August 12, 2016;

our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 filed on November 14, 2016;

our Current Reports on Form 8-K filed on January 7, 2016, January 22, 2016, January 25, 2016, January 28, 2016, February 9, 2016, February 23, 2016, March 23, 2016, April 5, 2016, April 18, 2016, April 28, 2016, May 3, 2016, May 27, 2016, June 13, 2016, July 5, 2016, July 22, 2016, August 19, 2016, August 24, 2016, October 5, 2016, and November 22, 2016; and



the description of our common stock contained in our Registration Statement on Form 8-A filed on February 7, 2014, including any amendment or report filed for the purpose of updating such description.

A statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or in any other subsequently filed document which is also incorporated in this prospectus modifies or replaces such statement. Any statements so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Amedica Corporation Attn: Investor Relations 1885 West 2100 South Salt Lake City, UT 84119.

You may also read and copy our annual, quarterly and current reports, and other SEC filings at our website, <http://www.amedica.com>, and at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at (800) SEC- 0330. Our SEC filings are also available to the public on the SEC's website at [www.sec.gov](http://www.sec.gov).

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, excluding, in each case, information deemed furnished and not filed, until all securities registered hereunder have been sold or the termination of the offering.

**PART II.****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the common stock being registered. The selling stockholders will not bear any portion of such expenses. All the amounts shown are estimates, except for the SEC registration fee.

SEC Registration Fee	\$94.81
Accounting Fees and Expenses	\$12,000.00
Legal Fees and Expenses	\$15,000.00
Total	\$27,094.81

**Item 15. Indemnification of Directors and Officers.**

Our amended and restated certificate of incorporation and amended and restated bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director, officer, employee or agent of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law against all expense, liability and loss (including attorneys' fees, judgments, fines, Employee Retirement Insurance Security Act excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered in connection with legal proceedings. These provisions limit the liability of our directors and officers to fullest extent permitted under Delaware law. A director or officer will not receive indemnification if he or she is found not to have acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interest.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he

reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reasonable cause to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that such person is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, Article Eighth of our amended and restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

from any breach of the director's duty of loyalty to us or our stockholders;

from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the Delaware General Corporation Law; or

from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers. We have entered into indemnification agreements with certain of our executive offices and directors. These agreements, among other things, indemnify and advance expenses to our directors and officers for certain expenses, including attorney's fees, judgments, fines and settlement amounts incurred by any such person in any action or proceeding, including any action by us arising out of such person's services as our director or officer, or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We have entered into agreements to indemnify all of our directors and officers.

**Item 16. Exhibits.**

Exhibit Number	Exhibit Description	Incorporated by			
		Filed herewith	Reference herein from	Filing Date	SEC File/Reg. Number
3.1	Restated Certificate of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	2/20/14	001-33624
3.1.1	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	1/22/16	001-33624
3.2	Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.1)	2/20/14	001-33624
4.1	Form of Common Stock Certificate of the Registrant		Amendment No. 3 to Form S-1 (Exhibit 4.1)	1/29/14	333-192232
5.1	Opinion of Dorsey & Whitney LLP	X			
23.1	Consent of Mantyla McReynolds, LLC, Independent Registered Public Accounting Firm				X
23.2	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1)				
24.1	Power of Attorney (included on the signature page of this Registration Statement)				

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however, That:*

(A) Paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

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.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Salt Lake City, State of Utah, on November 25, 2016.

### AMEDICA CORPORATION

BY: */s/ B. Sonny Bal*

B. Sonny Bal

President and Chief Executive Officer

*(principal executive officer and principal financial officer)*

### POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints B. Sonny Bal, his or her true and lawful attorney-in-fact and agent with full powers of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his or her 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 has been signed by the following persons in the capacities indicated on November 25, 2016.

*/s/ B. Sonny Bal* Chief Executive Officer, President and Chairman  
B. Sonny Bal of the Board *(principal executive officer and principal financial officer)*

*/s/ David Truetzel* Director  
David Truetzel

*/s/ Jeff White*      Director  
Jeff White

*/s/ Eric Stookey*      Director  
Eric Stookey



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