Tornier N.V.
Form S-3
October 17, 2012
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As filed with the Securities and Exchange Commission on October 17, 2012

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

TORNIER N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	98-0509600
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

Fred. Roeskestraat 123

1076 EE Amsterdam, The Netherlands

(+ 31) 20 675 4002

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

Kevin M. Klemz

Vice President, Chief Legal Officer and Secretary

Tornier N.V.

Fred. Roeskestraat 123

1076 EE Amsterdam, The Netherlands

(+ 31) 20 675 4002

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

Copies to:

Amy E. Culbert, Esq.

Oppenheimer Wolff & Donnelly LLP

Campbell Mithun Building, Suite 2000

222 South Ninth Street

Minneapolis, Minnesota 55402

(612) 607-7000

Approximate date of commencement of proposed sale to the public: **From time to time after this registration statement becomes effective as determined by the selling shareholders.**

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 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 or 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 x (Do not check if a smaller reporting company)	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of each class of Securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Ordinary shares, par value 0.03 per share	1,941,270	$18.91	$36,709,415	$5,007.16

(1) The amount to be registered hereunder consists of an aggregate of 1,941,270 ordinary shares to be sold by the selling shareholders named in this registration statement. In addition, pursuant to Rule 416 under the Securities Act of 1933, this registration statement includes an indeterminate number of additional shares that may be offered and sold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based upon the average of the high and low sale prices of the registrant s ordinary shares on October 15, 2012, as reported on the NASDAQ Global Select 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.

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The information in this prospectus is not complete and may be changed. The selling shareholders named in this prospectus 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 the selling shareholders named in this prospectus are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 17, 2012

Prospectus

1,941,270 Shares

Ordinary Shares

This prospectus relates to the resale, from time to time, of up to an aggregate of 1,941,270 ordinary shares of Tornier N.V. by the selling shareholders named in this prospectus and any prospectus supplement, including their donees, pledges, transferees or other successors in interest. The selling shareholders acquired the shares offered for resale under this prospectus at the closing of our acquisition of OrthoHelix Surgical Designs, Inc. on October 4, 2012. We issued the ordinary shares to the selling shareholders pursuant to an exemption from the registration requirements of the Securities Act of 1933.

The registration of the ordinary shares covered by this prospectus does not necessarily mean that any of the shares will be offered or sold by the selling shareholders. The timing and amount of any sales are within the sole discretion of the selling shareholders. We will not receive any proceeds from sales of the shares offered by the selling shareholders, but we will incur expenses in connection with the offering.

The ordinary shares offered under this prospectus may be sold by the selling shareholders through public or private transactions, on or off the NASDAQ Stock Market, at prevailing market prices or at privately negotiated prices. For more information on the times and manner in which the selling shareholders may sell the ordinary shares under this prospectus, please see the section entitled Plan of Distribution, beginning on page 49 of this prospectus.

Our ordinary shares trade on the NASDAQ Global Select Market under the symbol TRNX. On October 16, 2012, the last reported sale price of our ordinary shares was $18.63 per share.

Investing in our ordinary shares involves a high degree of risk. We refer you to the section entitled Risk Factors beginning on page 5 of this prospectus before you make an investment decision.

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

The date of this prospectus is , 2012.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, under the Securities Act of 1933, as amended, or the Securities Act, using a shelf registration or continuous offering process. Under this shelf process, certain selling shareholders from time to time may sell the ordinary shares described in this prospectus in one or more offerings. In certain circumstances, we may provide a prospectus supplement that will contain specific information about the terms of a particular offering by one or more of the selling shareholders. We also may provide a prospectus supplement to add information to, or update or change information contained in, this prospectus. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus or any prospectus supplement the statement in the later-dated document modifies or supersedes the earlier statement.

You should read both this prospectus and any applicable prospectus supplement together with the additional information about our company to which we refer you in the section of this prospectus entitled Where You Can Find Additional Information. You should rely only on the information contained in or incorporated by reference into this prospectus and any prospectus supplement. Neither we nor the selling shareholders have authorized any dealer, sales person or other person to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact included in this prospectus that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, operating results and business.

We have identified some of these forward-looking statements with words like believe, may, will, should, could, expect, intend, plan, anticipate, estimate or continue other words and terms of similar meaning and the use of future dates. These forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially from those matters expressed or implied by our forward-looking statements. Forward-looking statements (including oral representations) are only predictions or statements of current plans and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks described under the heading Risk Factors elsewhere in this prospectus. For more information regarding risks, uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see Risk Factors. The risks and uncertainties described under the heading Risk Factors are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements, except as otherwise required by law. We advise you, however, to consult any further disclosures we make on related subjects in our future annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the SEC.

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. Because this section is only a summary, it does not contain all of the information that may be important to you or that you should consider before making an investment decision. For a more complete understanding of this offering, we encourage you to read this entire prospectus, including the more detailed information and consolidated financial statements and the notes thereto incorporated by reference into this prospectus.

Unless the context specifically indicates otherwise, references in this prospectus to we, us, our, the Company and Tornier refer collectively to Tornier N.V. and its consolidated subsidiaries.

Our Business

We are a global medical device company focused on surgeons that treat musculoskeletal injuries and disorders of the shoulder, elbow, wrist, hand, ankle and foot. We refer to these surgeons as extremity specialists. We sell to this extremity specialist customer base a broad line of joint replacement, trauma, sports medicine and biologic products to treat extremity joints. Our motto of specialists serving specialists encompasses this focus. In certain international markets, we also offer joint replacement products for the hip and knee. We currently sell over 110 product lines in approximately 35 countries.

We believe we are differentiated by our full portfolio of upper and lower extremity products, our extremity-focused sales organization and our strategic focus on extremities. We further believe that we are well positioned to benefit from the opportunities in the extremity products marketplace as we are among the global leaders in the shoulder and ankle joint replacement markets. We also have expanded our technology base and product offering to include: new joint replacement products based on new designs and materials; improved trauma products based on innovative designs; and proprietary biologic materials for soft tissue repair. In the United States, which is the largest orthopaedic market, we believe that our focused, specialists serving specialists distribution approach is strategically aligned with what we believe is an ongoing trend in orthopaedics for surgeons to specialize in certain parts of the anatomy or certain types of procedures.

Our principal products are organized in four major categories: upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics, and large joints and other. Our upper extremity joints and trauma products include joint replacement and bone fixation devices for the shoulder, hand, wrist and elbow. Our lower extremity joints and trauma products include joint replacement and bone fixation devices for the foot and ankle. Our sports medicine and biologics product category includes products used across several anatomic sites to repair or regenerate soft tissue. Our large joints and other products include hip and knee joint replacement implants and ancillary products.

In the United States, we sell products from our upper extremity joints and trauma, lower extremity joints and trauma, and sports medicine and biologics product categories; we do not actively market large joints in the United States. While we market our products to extremity specialists, our revenue is generated from sales to healthcare institutions and distributors. We sell through a focused sales channel consisting of a network of mostly independent commission-based sales agencies, with some direct sales organizations in certain territories. Internationally, in select markets, we sell our full product portfolio, including upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics and large joints. We utilize several distribution approaches depending on the individual market requirements, including direct sales organizations in the largest European markets and Australia, and independent distributors for most other international markets. For the six months ended July 1, 2012, we generated revenue of $140.5 million, 54% of which was in the United States and 46% of which was international.

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Recent Developments

On August 23, 2012, we entered into an agreement and plan of merger (which we refer to as the merger agreement) with OrthoHelix Surgical Designs, Inc., a Delaware corporation (which we refer to as OrthoHelix), Oscar Acquisition Corp., a Delaware corporation and wholly owned subsidiary of Tornier N.V. (which we refer to as merger sub), and MCPF GP Holdings, Inc., solely in its capacity as representative of OrthoHelix s equity holders. On October 4, 2012, pursuant to the terms of the merger agreement, merger sub merged with and into OrthoHelix, and OrthoHelix continued as the surviving entity and a wholly owned subsidiary of Tornier. In the transaction, we paid consideration consisting of $100 million cash and 1,941,270 of our ordinary shares (which was determined to be equal to $35 million divided by the average closing sale price per ordinary share during the five trading days immediately prior to and after the date of our initial public announcement of the merger agreement). In addition, we agreed to make additional earnout payments in cash of up to an aggregate of $20 million based upon our sales of lower extremity joints and trauma products during fiscal years 2013 and 2014. A portion of the transaction consideration consisting of $11 million cash was deposited with an escrow agent to fund payment obligations with respect to a post-closing working capital adjustment and post-closing indemnification obligations of OrthoHelix s former equity holders. In addition, a portion of the earnout payments are subject to certain rights of set-off for post-closing indemnification obligations of OrthoHelix s equity holders.

As part of the transaction, on October 4, 2012, Tornier N.V. and our U.S. operating subsidiary, Tornier, Inc. (which we refer to as Tornier USA), entered into a credit agreement with Bank of America, N.A., as Administrative Agent, SG Americas Securities, LLC, as Syndication Agent, BMO Capital Markets and JPMorgan Chase Bank, N.A., as Co-Documentation Agents, Merrill Lynch, Pierce, Fenner & Smith Incorporated and SG Americas Securities, LLC, as Joint Lead Arrangers and Joint Bookrunners, and the other lenders party thereto. The credit agreement provides for an aggregate credit commitment to Tornier USA, as borrower, of U.S. $145 million, consisting of: (1) a senior secured term loan facility to Tornier USA denominated in dollars in an aggregate principal amount of up to U.S. $75 million; (2) a senior secured term loan facility to Tornier USA denominated in euros in an aggregate principal amount of up to the U.S. dollar equivalent of U.S. $40 million; and (3) a senior secured revolving credit facility to Tornier USA denominated at the election of Tornier USA, in U.S. dollars, euros, pounds, sterling and yen in an aggregate principal amount of up to the U.S. dollar equivalent of U.S. $30 million. Funds available under the revolving credit facility may be used for general corporate purposes. The borrowings under the credit facility were used at the closing of the merger transaction described above to pay the consideration for such merger, and such fees, costs and expenses incurred in connection with the merger and the credit agreement and to repay prior existing indebtedness of Tornier and its subsidiaries. The credit agreement contains customary covenants, including financial covenants which require Tornier to maintain minimum interest coverage and maximum total net leverage ratios, and customary events of default. The obligations under the credit agreement are guaranteed by Tornier, Tornier USA and certain other specified subsidiaries of Tornier, and subject to certain exceptions, are secured by a first priority security interest in substantially all of the assets of Tornier, Tornier and certain specified existing and future subsidiaries of Tornier.

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Risk Factors

Investing in our company entails a high degree of risk, as more fully described in the Risk Factors section of this prospectus. You should carefully consider such risks before deciding to invest in our ordinary shares. Our principal risks include:

- We have a history of operating losses and negative cash flow;
- If we do not successfully develop and market new products and technologies and implement our business strategy, our business and results of operations will be adversely affected;
- We rely on our independent sales agencies and their representatives to market and sell our products;
- We may be unable to compete successfully against our existing or future competitors;
- We derive a significant portion of our sales from operations in international markets that are subject to political, economic and social instability;
- If we fail to maintain regulatory clearances and approvals, or are unable to obtain, or experience significant delays in obtaining, U.S. Food and Drug Administration, or FDA, clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer;
- Our recent acquisition of OrthoHelix may not be successful, we may not be able to integrate successfully our commercial organizations, including in particular our distribution and sales representative arrangements, and the benefits and synergies we anticipated to our business and operating results as a result of such acquisition may not materialize; and
- Your rights as a holder of ordinary shares will be governed by Dutch law and will differ from the rights of shareholders under U.S. law.

Corporate Information

Our principal executive offices are located at Fred. Roeskestraat 123, 1076 EE Amsterdam, The Netherlands. Our telephone number at this address is (+ 31) 20 577 1177. Our agent for service of process in the United States is CT Corporation, 1209 Orange St., Wilmington, DE 19801. Our website is located at www.tornier.com. The information contained on or connected to our website is not a part of this prospectus.

This prospectus contains references to our trademarks Aequalis®, Affiniti®, Ascend®, Simpliciti , Salto®, Salto Talaris® and Tornier® among others. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

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The Offering

Ordinary shares offered by Tornier N.V.	0 ordinary shares
Ordinary shares offered by the selling shareholders	1,941,270 ordinary shares
Ordinary shares outstanding[1]	41,718,896 ordinary shares (as of October 15, 2012)
Use of proceeds	All of the ordinary shares being offered under this prospectus are being sold by the selling shareholders. Accordingly, we will not receive any proceeds from the sale of these shares.
NASDAQ Global Select Market symbol	TRNX
Risk factors	Investing in our ordinary shares involves a high degree of risk. See Risk Factors, beginning on page 5 for a discussion of factors you should carefully consider before investing in our ordinary shares.

[1] The number of ordinary shares outstanding is based on ordinary shares outstanding as of October 15, 2012 and excludes:

- 3,953,576 ordinary shares issuable upon exercise of options to purchase ordinary shares as of October 15, 2012, at a weighted average exercise price of $18.23 per ordinary share;
- 381,842 ordinary shares issuable upon vesting of outstanding restricted stock units as of October 15, 2012;
- 2,586,030 ordinary shares available for future issuance under the Tornier N.V. 2010 Incentive Plan as of October 15, 2012; and
- 325,285 ordinary shares available for future issuance under the Tornier N.V. 2010 Employee Stock Purchase Plan as of October 15, 2012.

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RISK FACTORS

An investment in our ordinary shares involves a high degree of risk. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below and in the documents incorporated by reference into this prospectus and any prospectus supplement, before making an investment in our ordinary shares. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our ordinary shares could decline, and you may lose all or part of your investment. Further, additional risks not currently known to us or that we currently believe are immaterial also may have a material adverse effect on our business, financial condition and results of operations. See also Special Note Regarding Forward-Looking Statements elsewhere in this prospectus.

Risks Related to Our Business and Our Industry

We have a history of operating losses and negative cash flow and may never achieve profitability.

We have a history of operating losses and at July 1, 2012, we had an accumulated deficit of $219.2 million. Our ability to achieve profitability will be influenced by many factors, including the extent and duration of our future operating losses, the level and timing of future revenue and expenditures, market acceptance of new products, the results and scope of ongoing research and development projects, competing technologies and market and regulatory developments. As a result, we may continue to incur operating losses for the foreseeable future. These losses will continue to have an adverse impact on shareholders equity, and we may never achieve or sustain profitability.

If we do not successfully develop and market new products and technologies and implement our business strategy, our business and operating results may be adversely affected.

We may not be able to successfully implement our business strategy. To implement our business strategy we need to, among other things, develop and introduce new extremity joint products, find new applications for and improve our existing products, properly identify and anticipate our surgeons and their patients needs, obtain regulatory clearances or approvals for new products and applications and educate surgeons about the clinical and cost benefits of our products.

We are continually engaged in product development and improvement programs, and we expect new products to account for a significant portion of our future growth. If we do not continue to introduce new products and technologies, or if those products and technologies are not accepted, we may not be successful. Moreover, research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or innovation. Demand for our products also could change in ways we may not anticipate due to evolving customer needs, changing demographics, slow industry growth rates, evolving surgical philosophies and evolving industry standards, among others. Additionally, our competitors new products and technologies may precede our products to market, may be more effective or less expensive than our products or may render our products obsolete.

Our targeted surgeons practice in areas such as shoulder, upper extremities, lower extremities, sports medicine and reconstructive and general orthopaedics, and our strategy of focusing exclusively on these surgeons may not be successful. In addition, we are seeking to increase our international revenue and will need to increase our worldwide direct sales force and enter into distribution agreements with third parties in order to do so. All of this may result in additional or different foreign regulatory requirements, with which we may not be able to comply. Moreover, even if we successfully implement our business strategy, our operating results may not improve. We may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors.

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We rely on our distributors, independent sales agencies and their representatives to market and sell our products. A failure to maintain our existing relationships with our distributors, independent sales agencies and their representatives could have an adverse effect on our operation results.

In the United States, we sell our products primarily through a sales channel consisting of mostly independent commission-based sales agencies, which utilize several sales representatives, with some direct sales organizations in certain territories. Internationally, we utilize several distribution approaches depending on the individual market requirements, including direct sales organizations in the largest European markets and Australia, and independent distributors for most other international markets. Our distributors and sales agencies do not sell our products exclusively and may offer similar products from other orthopaedic companies. In 2011 and during the six months ended July 1, 2012, no individual distributor or sales agency accounted for more than 7% of our global revenue. Our success depends largely upon our ability to motivate our distributors and sales agencies to sell our products. Additionally, we depend on their sales and service expertise and relationships with the surgeons in the marketplace. Our distributors and independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products or may focus their sales efforts on other products that produce greater commissions for them. If our relationship with any of our distributors or sales agencies terminated, we could enter into agreements with existing distributors and sales agencies to take on the related sales, contract with distributors and new sales agencies, or hire direct sales representatives or a combination of these options. A failure to maintain our existing relationships with our distributors and independent sales agencies and their representatives could have an adverse effect on our operations. We do not control our distributors or independent sales agencies and they may not be successful in implementing our marketing plans.

During 2012, we terminated our sales relationships with a few independent sales agencies in the United States that were not performing to our expectations. This has resulted in some disruption in our United States sales channel and adversely affected our revenues during 2012. We may terminate our sales relationships with additional independent sales agencies and some of our distributors that are not performing to our expectations and it is possible that such actions will result in further disruption in our United States sales channel, disruption in certain countries outside the United States and adversely affect our revenues during the remainder of 2012 and 2013. It is also possible that we may incur future charges and cash expenditures in connection with such independent sales agency and distributor changes and transitions, which charges and cash expenditures would adversely affect our operating results.

If our facilities consolidation initiative is not implemented properly or is unsuccessful, our business and operating results might be adversely affected. In addition, the initiative could result in deficiencies in our internal control over financial reporting and other controls and procedures.

We have commenced a facilities consolidation initiative pursuant to which we intend to consolidate a number of our facilities in France, Ireland and the United States. The facilities consolidation initiative is driven by our strategy to drive operational productivity and to realize operating costs savings beginning in 2013. Under the initiative, we consolidated our Dunmanway, Ireland manufacturing facility into our Macroom, Ireland manufacturing facility during the second quarter of 2012. We also leased a new facility located in Bloomington, Minnesota to use as our U.S. business headquarters and for the consolidation of our Minneapolis-based marketing, training, regulatory, clinical, supply chain and corporate functions with our Stafford, Texas-based distribution operations, which are expected to be finalized during the fourth quarter of 2012. During the third quarter of 2012, we consolidated our St. Ismier, France manufacturing facility into our existing Montbonnot, France manufacturing facility. We anticipate that, in connection with implementing the facilities consolidation initiative, we will record pre-tax charges, comprised of one-time employee termination costs; facility closure, moving and related expenses; fixed asset write-offs net of anticipated proceeds from the sale of facilities in Stafford, Texas and Dunmanway, Ireland; and other miscellaneous related charges. We expect to record substantially all of the charges during 2012. During the six months ended July 1, 2012, we recorded $2.5 million of expense related to the facilities consolidation initiative.

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The anticipated timing of our various activities under the initiative and our estimates relating to the amount of charges, cash expenditures and cash savings that we expect to realize in connection with the initiative may change as we finalize and implement the initiative. Any increase in the amount of charges or cash expenditures incurred in connection with the initiative would adversely affect our operating results and could disappoint investors who had expected lower amounts. Similarly, any decrease in our anticipated cash savings that we expect to realize in connection with the initiative also could adversely affect our operating results and disappoint investors who had expected higher cash savings. In addition, there can be no assurance that we will implement the initiative on a timely basis or in a manner that will produce the anticipated operational efficiencies, expense savings and other benefits that we believe should positively impact our business and operating results. If the initiative is not implemented properly or is unsuccessful, we might experience business disruptions or our business and operating results might otherwise be adversely affected. For example, the facility consolidations initiative may have an adverse impact on our relationships with our employees, major customers and vendors. In addition, the initiative could result in deficiencies in our internal control over financial reporting and other controls and procedures. The initiative may result in unanticipated expenses and charges, including litigation expenses, and have unintended impacts on our business, including in particular our new product development efforts. In addition, if the initiative is unsuccessful and does not produce the anticipated operational efficiencies, expense savings and other benefits, further restructuring activities might become necessary, resulting in additional future charges.

We may be unable to compete successfully against our existing or potential competitors, in which case our revenue and operating results may be negatively affected and we may not grow.

The market for orthopaedic devices is highly competitive and subject to rapid and profound technological change. Our success depends, in part, on our ability to maintain a competitive position in the development of technologies and products for use by our customers. We face competition from large diversified orthopaedic manufacturers, such as DePuy Orthopaedics, Inc., a Johnson & Johnson subsidiary, Zimmer Corporation and Stryker Corporation, and established mid-sized orthopaedic manufacturers, such as Arthrex, Inc., Wright Medical Group, Inc. and ArthroCare Corporation. Many of the companies developing or marketing competitive orthopaedic products enjoy several competitive advantages, including:

- greater financial and human resources for product development and sales and marketing;
- greater name recognition;
- established relationships with surgeons, hospitals and third-party payors;
- broader product lines and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage;
- established sales and marketing and distribution networks; and
- more experience in conducting research and development, manufacturing, preparing regulatory submissions and obtaining regulatory clearance or approval for products.

We also compete against smaller, entrepreneurial companies with niche product lines. Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearances or approvals for competing products more rapidly than us and develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive. We also compete with other organizations in recruiting and retaining qualified scientific and management

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personnel, as well as in acquiring technologies and technology licenses complementary to our products or advantageous to our business. If our competitors are more successful than us in these matters, we may be unable to compete successfully against our existing or future competitors.

We derive a significant portion of our revenue from operations in international markets that are subject to political, economic and social instability.

We derive a significant portion of our revenue from operations in international markets. Our international distribution system consists of 10 direct sales offices and approximately 30 distribution partners, who sell in approximately 35 countries. Most of these countries are, to some degree, subject to political, economic and social instability. For the six months ended July 1, 2012 and the year ended January 1, 2012, approximately 46% of our revenue was derived from our international operations. In 2012, we opened a direct sales office in Japan and we intend to further expand our international operations into key markets, such as Brazil and China. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations on orthopaedic implants and biologics products;
- the imposition of costly and lengthy new export license requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with that country, company, person or entity;
- economic instability, including the European sovereign debt crisis and the austerity measures taken and to be taken by certain countries in response to such crisis, and the currency risk between the U.S. dollar and foreign currencies in our target markets;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed upon us;
- a shortage of high-quality international salespeople and distributors;
- loss of any key personnel who possess proprietary knowledge or are otherwise important to our success in international markets;
- changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may require us to sell our products at lower prices;
- unexpected changes in foreign regulatory requirements;
- differing local product preferences and product requirements;
- changes in tariffs and other trade restrictions;

work stoppages or strikes in the healthcare industry;

difficulties in enforcing and defending intellectual property rights;

foreign exchange controls that might prevent us from repatriating cash earned in countries outside the Netherlands.;

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complex data privacy requirements and labor relations laws; and

exposure to different legal and political standards.

Not only are we subject to the laws of other jurisdictions, we also are subject to U.S. laws governing our activities in foreign countries, including various import-export laws, customs and import laws, anti-boycott laws and embargoes. For example, the FDA Export Reform and Enhancement Act of 1996 requires that, when exporting medical devices from the United States for sale in a foreign country, depending on the type of product being exported, the regulatory status of the product and the country to which the device is exported, we must ensure, among other things, that the device is produced in accordance with the specifications of the foreign purchaser; not in conflict with the laws of the country to which it is intended for export; labeled for export; and not offered for sale domestically. In addition, we must maintain records relevant to product export and, if requested by the foreign government, obtain a certificate of exportability. In some instances, prior notification to or approval from the FDA is required prior to export. The FDA can delay or deny export authorization if all applicable requirements are not satisfied. Imports of approved medical devices into the United States also are subject to requirements including registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events, and premarket notification 510(k) clearance or premarket approval, or PMA, among others and if applicable. If our business activities were determined to violate these laws, regulations or rules, we could suffer serious consequences.

In addition, a portion of our international revenue is made through distributors. As a result, we are dependent upon the financial health of our distributors. If a distributor were to go out of business, it would take substantial time, cost and resources to find a suitable replacement and the products held by such distributor may not be returned to us or to a subsequent distributor in a timely manner or at all.

Any material decrease in our foreign revenue may negatively affect our profitability. We generate our international revenue primarily in Europe, where healthcare regulation and reimbursement for orthopaedic medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries. In addition, many of the economies in Europe have undergone recessions which have threatened their ability to service their sovereign debt obligations. Several of these countries have implemented austerity measures, which have adversely affected our sales and may continue to adversely affect our sales.

Disruption and turmoil in global credit and financial markets, which may be exacerbated by the inability of certain countries to continue to service their sovereign debt obligations and certain austerity measures countries have implemented, and the possible negative implications of such events to the global economy, may negatively impact our business, operating results and financial condition.

The downgrade of the U.S. credit rating and the credit ratings of several European countries and the possibility that certain European Union member states will default on their debt obligations have contributed to significant uncertainty about the stability of global credit and financial markets. The credit and economic conditions within certain European Union countries in particular, including France, Greece, Ireland, Italy, Portugal and Spain, have contributed to the instability in global credit and financial markets. The possibility that such EU member states will default on their debt obligations, the continued uncertainty regarding international and the European Union s financial support programs and the possibility that other EU member states may experience similar financial troubles could further disrupt global credit and financial markets. While the ultimate outcome of these events cannot be predicted, it is possible that such events could have a negative effect on the global economy as a whole, and our business, operating results and financial condition, in particular. For example, if the European sovereign debt crisis continues or worsens, the negative implications to the global economy and us could be significant. Since a significant amount of our trade receivables are with hospitals that are dependent upon

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governmental health care systems in many countries, repayment of such receivables is dependent upon the financial stability of the economies of those countries. A deterioration of economic conditions in such countries may increase the average length of time it takes for us to collect on our outstanding accounts receivable in these countries or even our ability to collect such receivables.

In addition, if the European sovereign debt crisis continues or worsens, the value of the Euro could deteriorate or lead to the re-introduction of individual currencies in one or more Eurozone countries, or, in more extreme circumstances, the possible dissolution of the Euro currency entirely, all of which could negatively impact our business, operating results and financial condition in light of our substantial operations in and revenues derived from customers in the European Union. Should the Euro dissolve entirely, the legal and contractual consequences for holders of Euro-denominated obligations would be determined by laws in effect at such time. These potential developments, or market perceptions concerning these and related issues, could adversely affect the value of our Euro-denominated assets and obligations. In addition, concerns over the effect of this financial crisis on financial institutions in Europe and globally could lead to tightening of the credit and financial markets, which could negatively impact the ability of companies to borrow money from their existing lenders, obtain credit from other sources or raise financing to fund their operations. This could negatively impact our customers ability to purchase our products, our suppliers ability to provide us with materials and components and our ability, if needed, to finance our operations on commercially reasonable terms, or at all. We believe that European governmental austerity policies have reduced and may continue to reduce the amount of money available to purchase medical products, including our products. These austerity measures could negatively impact overall procedure volumes and result in increased pricing pressure for our products and the products of our competitors. Any or all of these events, as well as any additional austerity measures that may be taken which, among other things, could result in decreased utilization, pricing and reimbursement, could negatively impact our business, operating results and financial condition.

Weakness in the global economy is likely to adversely affect our business until an economic recovery is underway.

Many of our products are used in procedures covered by private insurance, and some of these procedures may be considered elective. We believe the global economic downturn may reduce the availability or affordability of private insurance or may affect patient decisions to undergo elective procedures. If current economic conditions do not continue to recover or worsen, we expect that increasing levels of unemployment and pressures to contain healthcare costs could adversely affect the global growth rate of procedure volume, which could have a material adverse effect on our revenue and operating results.

Fluctuations in foreign currency rates could result in declines in our reported revenue and earnings.

A substantial portion of our revenue outside the United States is generated in Europe and other countries in Latin America and Asia where the amounts are denominated in currencies other than the U.S. dollar. For purposes of preparing our consolidated financial statements, these amounts are converted into U.S. dollars, the value of which varies with currency exchange rate fluctuations. For revenue not denominated in U.S. dollars, if there is an increase in the value of the U.S. dollar relative to the specified foreign currency, we will receive less in U.S. dollars than before the increase in the exchange rate, which could negatively impact our operating results. Although we address currency risk management through regular operating and financing activities, those actions may not prove to be fully effective.

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Our business plan relies on assumptions about the market for our products, which, if incorrect, may adversely affect our revenue.

We believe that the aging of the general population and increasingly active lifestyles will continue and that these trends will increase the need for our products. We anticipate that the market for our extremity products in particular will continue to grow. The actual demand for our products, however, could differ materially from our projected demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize, or if non-surgical treatments gain more widespread acceptance as a viable alternative to our orthopaedic implants.

Our upper extremity joints and trauma products, including in particular our shoulder products, generate a significant portion of our revenue. Accordingly, if revenue of these products were to decline, our operating results would be adversely affected.

Our upper extremity joints and trauma products, which includes joint implants and bone fixation devices for the shoulder, hand, wrist and elbow, generate a significant portion of our revenue. During the six months ended July 1, 2012 and the fiscal year ended January 1, 2012, our upper extremity joints and trauma products generated approximately 64% and 63%, respectively, of our revenue. We expect the shoulder to continue to be the largest and most important product category for us for the foreseeable future. A decline in revenue from these products as a result of increased competition, regulatory matters, intellectual property matters or any other reason would negatively impact our operating results.

We obtain some of our products through private-label distribution agreements that subject us to minimum performance and other criteria. Our failure to satisfy those criteria could cause us to lose those rights of distribution.

We have entered into private-label distribution agreements with manufacturers of some of our products. These manufacturers brand their products according to our specifications, and we may have exclusive rights in certain fields of use and territories to sell these products subject to minimum purchase, sales or other performance criteria. Though these agreements do not individually or in the aggregate represent a material portion of our business, if we do not meet these performance criteria, or fail to renew these agreements, we may lose exclusivity in a field of use or territory or cease to have any rights to these products, which could have an adverse effect on our revenue. Furthermore, some of these manufacturers may be smaller, undercapitalized companies that may not have sufficient resources to continue operations or to continue to supply us sufficient product without additional access to capital.

If our private-label manufacturers fail to provide us with sufficient supply of their products, or if their supply fails to meet appropriate quality requirements, our business could suffer.

Our private-label manufacturers are sole source suppliers of the products we purchase from them. Given the specialized nature of the products they provide, we may not be able to locate or establish additional or replacement manufacturers of these products. Moreover, these private-label manufacturers typically own the intellectual property associated with their products, and even if we could find a replacement manufacturer for the product, we may not have sufficient rights to enable the replacement party to manufacture the product. While we have entered into agreements with our private-label manufacturers to provide us sufficient quantities of products, we cannot assure you that they will do so, or that any products they do provide us will not contain defects in quality. Our private-label manufacturing agreements have terms expiring between this year and 2015 and are renewable under certain conditions or by mutual agreement. The agreements also include some or all of the following provisions allowing for termination under certain circumstances: (i) either party s uncured material breach of the terms and

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conditions of the agreement, (ii) either party filing for bankruptcy, being bankrupt or becoming insolvent, suspending payments, dissolving or ceasing commercial activity, (iii) our inability to meet market development milestones and ongoing sales targets, (iv) termination without cause, provided that payments are made to the distributor, (v) a merger or acquisition of one of the parties by a third party, (vi) the enactment of a government law or regulation that restricts either party s right to terminate or renew the contract or invalidates any provision of the agreement or (vii) the occurrence of a force majeure, including natural disaster, explosion or war.

We also rely on these private-label manufacturers to comply with the regulations of the FDA, the competent authorities of the Member States of the European Economic Area, or EEA, or foreign regulatory authorities and their failure to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Any quality control problems that we experience with respect to products manufactured by our private-label manufacturers, any inability by us to provide our customers with sufficient supply of products or any investigations or enforcement actions by the FDA, the competent authorities of the Member States of the EEA or other foreign regulatory authorities could adversely affect our reputation or commercialization of our products and adversely and materially affect our business and operating results.

We intend to bring in-house the manufacturing of some of our shoulder products during 2012. Should we encounter difficulties in manufacturing these or other products, it could adversely affect our business.

We intend to bring in-house the manufacturing of some of our shoulder products during 2012, including in particular our Ascend and Simpliciti shoulder products. The technology and the manufacturing process for our shoulder products is highly complex, involving a large number of unique parts, and we may encounter difficulties in manufacturing these products in-house. There is no assurance that we will be able to meet the volume and quality requirements associated with our shoulder products. Manufacturing and product quality issues may arise as we increase the scale of our production. If our products do not consistently meet our customers performance expectations, our reputation may be harmed, and we may be unable to generate sufficient revenue to become profitable. Any delay or inability in bringing in-house the manufacturing of some of our shoulder products could diminish our ability to sell our products, which could result in lost revenue and seriously harm our business, financial condition and operating results.

Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Our U.S. operations, including those of our U.S. based subsidiary, Tornier, Inc., are currently subject to the U.S. Foreign Corrupt Practices Act, or the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of off books slush funds from which such improper payments can be made. We also are currently subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development s Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. We either operate or plan to operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, such as China and

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Brazil, and we utilize a number of third-party sales representatives for whose actions we could be held liable under the FCPA. We inform our personnel and third-party sales representatives of the requirements of the FCPA and other anticorruption laws, including, but not limited to their reporting requirements. We also have developed and will continue to develop and implement systems for formalizing contracting processes, performing due diligence on agents and improving our recordkeeping and auditing practices regarding these regulations. However, there is no guarantee that our employees, third-party sales representatives or other agents have not or will not engage in conduct undetected by our processes and for which we might be held responsible under the FCPA or other anticorruption laws.

If our employees, third-party sales representatives or other agents are found to have engaged in such practices, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions. The SEC is currently in the midst of conducting an informal investigation of numerous medical device companies over potential violations of the FCPA. Although we do not believe we are currently a target, any investigation of any potential violations of the FCPA or other anticorruption laws by U.S. or foreign authorities also could have an adverse impact on our business, financial condition and operating results.

Certain foreign companies, including some of our competitors, are not subject to prohibitions as strict as those under the FCPA or, even if subjected to strict prohibitions, such prohibitions may be laxly enforced in practice. If our competitors engage in corruption, extortion, bribery, pay-offs, theft or other fraudulent practices, they may receive preferential treatment from personnel of some companies, giving our competitors an advantage in securing business, or from government officials, who might give them priority in obtaining new licenses, which would put us at a disadvantage.

If we lose one of our key suppliers, we may be unable to meet customer orders for our products in a timely manner or within our budget.

We use a number of suppliers for raw materials and select components that we need to manufacture our products. These suppliers must provide the materials and components to our standards for us to meet our quality and regulatory requirements. We obtain some key raw materials and select components from a single source or a limited number of sources. For example, we rely on one supplier for raw materials and select components in several of our products, including Poco Graphite, Inc., which supplies graphite for our pyrocarbon products, CeramTec AG, or CeramTec, which supplies ceramic for ceramic heads for hips, and Heymark Metals Ltd., which supplies Cobalt Chrome used in certain of our hip, shoulder and elbow products. Establishing additional or replacement suppliers for these components, and obtaining regulatory clearances or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business and operating results. We do not have contracts with our sole source suppliers (other than a Quality Assurance Agreement and Secrecy Agreement with CeramTec, which only relate to quality and confidentiality obligations of the parties and do not govern the purchase and receipt of CeramTec products) and instead rely on purchase orders. As a result, those suppliers may elect not to supply us with product or to supply us with less product than we need, and we will have limited rights to cause them to do otherwise. In addition, some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third parties could adversely and materially affect our reputation or commercialization of our products and adversely and materially affect our business, operating results and prospects. Furthermore, some of these suppliers are smaller companies. To the extent that any of these suppliers are, or become, undercapitalized and do not otherwise have sufficient resources to continue operations or to supply us sufficient product without additional access to capital, such a failure could adversely affect our business. We also may have

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difficulty obtaining similar components from other suppliers that are acceptable to the FDA, the competent authorities or notified bodies of the Member States of the EEA, or foreign regulatory authorities and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Furthermore, since many of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments of components to us. For example, all foreign importers of medical devices are required to meet applicable FDA requirements, including registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events, and premarket notification 510(k) clearance or PMA, if applicable. In addition, all imported medical devices also must meet Bureau of Customs and Border Protection requirements. While it is our policy to maintain sufficient inventory of materials and components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials.

Sales volumes may fluctuate depending on the season and our operating results may fluctuate over the course of the year.

Our business is seasonal in nature. Historically, demand for our products has been the lowest in our third quarter as a result of the European holiday schedule during the summer months. We have experienced and expect to continue to experience meaningful variability in our revenue and gross profit among quarters, as well as within each quarter, as a result of a number of factors, including, among other things:

- the number and mix of products sold in the quarter and the geographies in which they are sold;
- the demand for, and pricing of, our products and the products of our competitors;
- the timing of or failure to obtain regulatory clearances or approvals for products;
- costs, benefits and timing of new product introductions;
- the level of competition;
- the timing and extent of promotional pricing or volume discounts;
- changes in average selling prices;
- the availability and cost of components and materials;
- the number of selling days;
- fluctuations in foreign currency exchange rates
- the timing of patients use of their calendar year medical insurance deductibles; and

impairment and other special charges.

If product liability lawsuits are brought against us, our business may be harmed.

The manufacture and sale of orthopaedic medical devices exposes us to significant risk of product liability claims. In the past, we have had a small number of product liability claims relating to our products, none of which either individually, or in the aggregate, have resulted in a material negative impact on our business. In the future, we may be subject to additional product liability claims, some of

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which may have a negative impact on our business. Such claims could divert our management from pursuing our business strategy and may be costly to defend. Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize new products or product candidates.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product or product candidate which is the subject of any such claim.

Our inability to maintain adequate working relationships with external research and development consultants and surgeons could have a negative impact on our ability to market and sell new products.

We maintain professional working relationships with external research and development consultants and leading surgeons and medical personnel in hospitals and universities who assist in product research and development and training. We continue to emphasize the development of proprietary products and product improvements to complement and expand our existing product lines. It is possible that state and federal laws requiring us to disclose payments or other transfers of value, such as free gifts or meals, to physicians and other healthcare providers could have a chilling effect on these relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us. If we are unable to maintain these relationships, our ability to develop and sell new and improved products could decrease, and future operating results could be unfavorably affected.

We incur significant expenditures of resources to maintain relatively high levels of inventory and instruments, which can reduce our cash flows.

As a result of the need to maintain substantial levels of inventory and instruments, we are subject to the risk of obsolescence. The nature of our business requires us to maintain a substantial level of inventory and instruments. For example, our total consolidated inventory balances were $79.2 million and $79.9 million at July 1, 2012 and January 1, 2012, respectively, and our total consolidated instrument balances were $49.3 million at July 1, 2012 and January 1, 2012. In order to market effectively we often must maintain and bring our customers instrument kits, back-up products and products of different sizes. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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Our recent acquisition of OrthoHelix and any additional acquisitions and efforts to acquire and integrate other companies or product lines could adversely affect our operations and financial results.

On October 4, 2012, we acquired OrthoHelix, a privately-held company focused on developing and marketing specialty implantable screw and plate systems for the repair of small bone fractures and deformities predominantly in the foot and ankle. In addition, we may pursue additional acquisitions of other companies or product lines. A successful acquisition depends on our ability to identify, negotiate, complete and integrate such acquisition and to obtain any necessary financing. With respect to our recent acquisition of OrthoHelix and any future acquisitions, we may experience:

- difficulties in integrating OrthoHelix and its personnel and products, as well as the personnel and products of any other acquired companies, into our existing business;
- difficulties in integrating OrthoHelix s and Tornier s commercial organizations, including in particular distribution and sales representative arrangements;
- difficulties or delays in realizing the anticipated benefits of our acquisition of OrthoHelix or any additional acquired companies and their products;
- diversion of our management s time and attention from other business concerns;
- challenges due to limited or no direct prior experience in new markets or countries we may enter;
- the potential loss of key employees, including in particular sales and research and development personnel, of our company, OrthoHelix or any other business we may acquire;
- the potential loss of key customers, distributors, representatives, vendors and other business partners who choose not to do business with our company post-acquisition;
- inability to effectively coordinate sales and marketing efforts to communicate our capabilities post-acquisition and coordinate sales organizations to sell our combined products;
- inability to successfully develop new products and services on a timely basis that address our new market opportunities post-acquisition;
- inability to compete effectively against companies already serving the broader market opportunities expected to be available to us post-acquisition;
- difficulties in the assimilation of different corporate cultures, practices and sales and distribution methodologies, as well as in the assimilation and retention of geographically dispersed, decentralized operations and personnel;

unanticipated costs, litigation and other contingent liabilities;

incurrence of acquisition and integration related costs, accounting charges, or amortization costs for acquired intangible assets;

potential write-down of goodwill, acquired intangible assets and/or deferred tax assets; and

additional legal, financial and accounting challenges and complexities in areas such as intellectual property, tax planning, cash management and financial reporting.

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In addition, we may have to incur debt or issue equity securities to pay for any future acquisition, the issuance of which could involve restrictive covenants or be dilutive to our existing shareholders. Acquisitions also could materially impair our operating results by requiring us to amortize acquired assets. For example, as a result of our acquisition of OrthoHelix, we incurred additional indebtedness, including two senior secured term loans in the aggregate principal amount of $115 million. The proceeds of the term loans were used to fund our acquisition of OrthoHelix and retire certain then existing indebtedness.

In addition, effective internal controls are necessary for us to provide reliable and accurate financial reports and to effectively prevent fraud. The integration of acquired businesses is likely to result in our systems and controls becoming increasingly complex and more difficult to manage. We devote significant resources and time to comply with the internal control over financial reporting requirements of the Sarbanes-Oxley Act of 2002. However, we cannot be certain that these measures will ensure that we design, implement and maintain adequate control over our financial processes and reporting in the future, especially in the context of acquisitions of other businesses. Any difficulties in the assimilation of acquired businesses into our control system could harm our operating results or cause us to fail to meet our financial reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock and our access to capital.

All of the risks described above may be exacerbated if we effect multiple acquisitions during a short period of time.

If we do not achieve the contemplated benefits of our acquisition of OrthoHelix, our business and financial condition may be materially impaired.

We may not achieve the desired benefits from our recent acquisition of OrthoHelix. For any of the reasons described above and elsewhere in this prospectus and even if we are able to successfully operate OrthoHelix within our company, we may not be able to realize the revenue and other synergies and growth that we anticipate from the acquisition in the time frame that we currently expect, and the costs of achieving these benefits may be higher than what we currently expect, because of a number of risks, including, but not limited to:

- the possibility that the acquisition may not further our business strategy as we expected;
- the possibility that we may not be able to expand the reach and customer base for OrthoHelix s products as expected;
- the possibility that we may not be able to expand the reach and customer base for our products as expected; and
- the fact that the acquisition will substantially expand our lower extremity joints and trauma business, and we may not experience anticipated growth in that market.

As a result of these risks, the OrthoHelix acquisition may not contribute to our earnings as expected, we may not achieve expected revenue synergies or our return on invested capital targets when expected, or at all, and we may not achieve the other anticipated strategic and financial benefits of the transaction.

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If we cannot retain our key personnel, we may not be able to manage and operate successfully, and we may not be able to meet our strategic objectives.

Our success depends, in part, upon key managerial, scientific, sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, governmental entities and other organizations. There is no guarantee that we will be successful in retaining our current personnel or in hiring or retaining qualified personnel in the future. Loss of key personnel or the inability to hire or retain qualified personnel in the future could have a material adverse effect on our ability to operate successfully. Further, any inability on our part to enforce non-compete arrangements related to key personnel who have left the company could have a material adverse effect on our business.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors and officers liability insurance, property insurance and workers compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers.

If a natural or man-made disaster, including as a result of climate change or weather, adversely affects our manufacturing facilities or distribution channels, we could be unable to manufacture or distribute our products for a substantial amount of time and our revenue could decline.

We principally rely on three manufacturing facilities, two of which are in France and one of which is in Ireland. The facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. For example, the machinery associated with our manufacturing of pyrocarbon in one of our French facilities is highly specialized and would take substantial lead-time and resources to replace. We also maintain a warehouse in Stafford, Texas, which is in the process of being consolidated into our new facility in Bloomington, Minnesota, and a warehouse in Montbonnot, France. Both of these warehouses contain large amounts of our inventory. Our facilities, warehouses or distribution channels may be affected by natural or man-made disasters. Further, such may be exacerbated by climate change, as some scientists have concluded that climate change could result in the increased severity of and perhaps more frequent occurrence of extreme weather patterns. For example, in the event of a tornado at one of our warehouses, we may lose substantial amounts of inventory that would be difficult to replace. In the event our facilities, warehouses or distribution channels are affected by a disaster, we would be forced to rely on, among others, third-party manufacturers and alternative warehouse space and distribution channels, which may or may not be available, and our revenue could decline. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms or at all.

We may be unable to raise capital when needed, which would force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.

There is no guarantee that our anticipated cash flow from operations will be sufficient to meet all of our cash requirements. We intend to continue to make investments to support our business growth and may require additional funds to:

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expand the commercialization of our products;

fund our operations and clinical trials;

continue our research and development;

defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;

commercialize our new products, if any such products receive regulatory clearance or approval for commercial sale; and

acquire companies and in-license products or intellectual property.

We believe that our cash and cash equivalents balance of $61.4 million as of July 1, 2012 (which has subsequently been reduced due to the acquisition of OrthoHelix and retirement of our indebtedness outstanding prior to that acquisition), anticipated cash receipts generated from revenue of our products and available credit under our new $30 million senior secured revolving credit facility, will be sufficient to meet our anticipated cash requirements for the remainder of 2012. However, our future funding requirements will depend on many factors, including:

market acceptance of our products;

the scope, rate of progress and cost of our clinical trials;

the cost of our research and development activities;

the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;

the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

the cost of defending any claims of product liability, or other claims against us, such as contract liabilities;

the cost and timing of additional regulatory clearances or approvals;

the cost and timing of expanding our sales, marketing and distribution capabilities;

the cost and timing of expanding our product offering inventories;

our ability to collect amounts receivable from customers;

the effect of competing technological and market developments; and

the extent to which we acquire or invest in additional businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

In the event that we would require additional working capital to fund future operations, we could seek to acquire that through additional equity or debt financing arrangements which may or may not be available on favorable terms at such time. If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt, in addition to those under our existing credit facilities. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our shareholders. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

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The lack of the borrowing availability under our credit lines and our potential inability to obtain replacement sources of credit could materially affect our operations and financial condition.

Although we currently have available credit under our new $30 million senior secured revolving credit facility, our ability to draw on our credit facility may be limited by outstanding letters of credit or by operating and financial covenants under our new credit agreement. There can be no assurances that we will continue to have access to this portion or any of our credit lines if our operating and financial performance do not satisfy these covenants. If we do not satisfy these criteria, and if we are unable to secure necessary waivers or other amendments from the lenders of our credit lines, we will not have access to this credit.

Both the $30 million revolving credit facility and the aggregate $115 million of term loans under our new credit agreement are secured by all of our assets (subject to certain exceptions) and except to the extent otherwise permitted under the terms of our new credit agreement, our assets cannot be pledged as security for other indebtedness. These limits on our ability to offer collateral to other sources of financing could limit our ability to obtain other financing which could materially affect our operations and financial condition.

Although we believe that our operating cash flows, on-hand cash levels and access to credit will give us the ability to meet our financing needs for the foreseeable future, there can be no assurance that they will do so. The lack of the borrowing availability under our revolving credit facilities and our potential inability to obtain replacement sources of credit could materially affect our operations and financial condition.

We are leveraged financially, which could adversely affect our ability to adjust our business to respond to competitive pressures and to obtain sufficient funds to satisfy our future research and development needs, to protect and enforce our intellectual property and other needs.

We have indebtedness. In connection with our acquisition of OrthoHelix, we obtained senior secured term loans in the aggregate principal amount of $115 million and a senior secured $30 million revolving line of credit. The degree to which we are leveraged could have important consequences, including, but not limited to, the following:

- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, litigation, general corporate or other purposes may be limited;
- a substantial portion of our cash flows from operations in the future will be dedicated to the payment of principal and interest on our indebtedness, including the requirement that certain excess cash flows and certain net proceeds of asset dispositions (including from condemnation or casualty) and certain new indebtedness be applied to prepayment of our senior secured terms loans; and
- we may be more vulnerable to economic downturns, less able to withstand competitive pressures and less flexible in responding to changing business and economic conditions.

A failure to comply with the covenants and other provisions of our credit agreement could result in events of default under such agreement, which could require the immediate repayment of our outstanding indebtedness. If we are at any time unable to generate sufficient cash flows from operations to service our indebtedness when payment is due, we may be required to attempt to renegotiate the terms

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of the agreements relating to the indebtedness, seek to refinance all or a portion of the indebtedness or obtain additional financing. There can be no assurance that we will be able to successfully renegotiate such terms, that any such refinancing would be possible or that any additional financing could be obtained on terms that are favorable or acceptable to us.

Our new credit agreement contains restrictive covenants that may limit our operating flexibility.

The agreement relating to our new senior secured term loans and senior secured revolving credit facility contain operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens, make capital expenditures and conduct transactions with affiliates and financial covenants requiring us to meet certain financial ratios. We therefore may not be able to engage in any of the foregoing transactions or in any that would cause us to breach these financial covenants until our current debt obligations are paid in full or we obtain the consent of the lenders. There is no guarantee that we will be able to generate sufficient cash flow or revenue to meet these operating and financial covenants or pay the principal and interest on our debt. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance any such debt.

As a result of our acquisition of OrthoHelix, we may be required to make future earn-out payments of up to an aggregate of $20 million based upon our sales of lower extremity joints and trauma products during fiscal years 2013 and 2014, which payments may affect our liquidity and our financial results.

In connection with our recent acquisition of OrthoHelix, we agreed to made additional earnout payments of up to an aggregate of $20 million in cash based upon our sales of lower extremity joints and trauma products during fiscal years 2013 and 2014. A portion of the earnout payments will be subject to certain rights of set-off for post-closing indemnification obligations of OrthoHelix s equity holders. If we are required to make these payments, particularly at a time when we are experiencing financial difficulty, our liquidity, financial results and financial condition may be adversely affected.

Our operating results could be negatively impacted by future changes in the allocation of income to each of the entities through which we operate and to each of the income tax jurisdictions in which we operate.

We operate through multiple entities and in multiple income tax jurisdictions with different income tax rates both inside and outside the United States and the Netherlands. Accordingly, our management must determine the appropriate allocation of income to each such entity and each of these jurisdictions. Income tax audits associated with the allocation of this income and other complex issues, including inventory transfer pricing and cost sharing and product royalty arrangements, may require an extended period of time to resolve and may result in income tax adjustments if changes to the income allocation are required. Since income tax adjustments in certain jurisdictions can be significant, our future operating results could be negatively impacted by settlement of these matters.

Future changes in technology or market conditions could result in adjustments to our recorded asset balance for intangible assets, including goodwill, resulting in additional charges that could significantly impact our operating results.

Our consolidated balance sheet includes significant intangible assets, including goodwill and other acquired intangible assets. The determination of related estimated useful lives and whether these assets are impaired involves significant judgments. Our ability to accurately predict future cash flows related to these intangible assets may be adversely affected by unforeseen and uncontrollable events. In the highly competitive medical device industry, new technologies could impair the value of our intangible

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assets if they create market conditions that adversely affect the competitiveness of our products. We test our goodwill for impairment in the fourth quarter of each year, but we also test goodwill and other intangible assets for impairment at any time when there is a change in circumstances that indicates that the carrying value of these assets may be impaired. Any future determination that these assets are carried at greater than their fair value could result in substantial non-cash impairment charges, which could significantly impact our reported operating results.

If reimbursement from third-party payors for our products becomes inadequate, surgeons and patients may be reluctant to use our products and our revenue may decline.

In the United States, healthcare providers who purchase our products generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the cost of joint reconstructive procedures and products utilized in those procedures. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement. Our revenue depends largely on governmental healthcare programs and private health insurers reimbursing patients medical expenses. To contain costs of new technologies, third-party payors are increasingly scrutinizing new treatment modalities by requiring extensive evidence of clinical outcomes and cost-effectiveness. Currently, we are aware of several private insurers who have issued policies that classify procedures using our Salto Talaris Prosthesis and Conical Subtalar Implants as experimental or investigational and denied coverage and reimbursement for such procedures. Surgeons, hospitals and other healthcare providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. If we are not successful in reversing existing non-coverage policies or other private insurers issue similar policies, this could have a material adverse effect on our business and operations.

In addition, some healthcare providers in the United States have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer elective surgical procedures, including joint reconstructive surgeries, or by requiring the use of the least expensive implant available. Additionally, there is a significant likelihood of reform of the U.S. healthcare system, and changes in reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our products may cause our revenue to decline.

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

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted

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and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or operating results.

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

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, purchasing and inventory management. Currently, we have a non-interconnected information technology system; however, we have undertaken planning for the implementation of an upgrade of our systems, which could include the implementation of a new global enterprise resource planning system (ERP). We expect that this upgrade will take two to three years to implement; however, when complete it should enable management to better and more efficiently conduct our operations and gather, analyze, and assess information across all of our business and geographic locations. This upgrade will require the investment of significant human and financial resources. We may experience difficulties in implementing this upgrade in our business operations, or difficulties in operating our business under this upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain, and otherwise adequately service our customers, and lead to increased costs and other difficulties. In the event we experience significant disruptions as a result of this implementation of an upgraded information technology system, we may not be able to fix our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our operating results and cash flows.

Risks Related to Regulatory Environment

The sale of our products is subject to regulatory clearances or approvals and our business is subject to extensive regulatory requirements. If we fail to maintain regulatory clearances and approvals, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities, such as those of the European Union and the competent authorities of the Member States of the EEA. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, packaging, content and language of instructions for use, and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;

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recordkeeping procedures;

advertising and promotion;

recalls and field corrective actions;

post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; and

product import and export.

Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that the proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology and safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and PMA processes can be expensive and lengthy and entail significant user fees, unless exempt. The FDA s 510(k) clearance process usually takes from three to 12 months, but may take longer. The PMA pathway is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to five years, or even longer, from the time the application is filed with the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

Most of our currently commercialized products have received premarket clearances under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our revenue to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we do not currently market any devices under PMA, we cannot assure you that the FDA will not demand that we obtain a PMA prior to marketing or that we will be able to obtain the 510(k) clearances with respect to future products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

we may not be able to demonstrate to the FDA s satisfaction that our products are safe and effective for their intended users;

the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;

the manufacturing process or facilities we use may not meet applicable requirements; and

changes in FDA clearance or approval policies or the adoption of new regulations may require additional data.

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Any delay in, or failure to receive or maintain, clearances or approvals for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other governmental authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could lead governmental authorities or a court to take action against us, including:

- issuing untitled letters or public warning letters to us;
- imposing fines and penalties on us;
- obtaining an injunction preventing us from manufacturing or selling our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our products into the market;
- delaying pending requests for clearance or approval of new uses or modifications to our existing products;
- recalling, detaining or seizing our products; or
- withdrawing or denying approvals or clearances for our products.

If we fail to obtain and maintain regulatory clearances or approvals, our ability to sell our products and generate revenue will be materially harmed.

Outside of the United States, our medical devices must comply with the laws and regulations of the foreign countries in which they are marketed, and compliance may be costly and time-consuming.

To market and sell our products in other countries, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive, and we cannot be certain that we will receive regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

In particular, in the EEA, which is composed of the 27 Member States of the EU plus Liechtenstein, Norway and Iceland, our medical devices must comply with the essential requirements of the EU Medical Devices Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, and Council Directive 90/385/EEC of 20 June 2009 relating to active implantable medical devices, as amended). Compliance with these requirements entitles us to affix the CE conformity mark to our medical devices, without which they cannot be marketed in the EEA.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices, or the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

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

Any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, technology, materials, packaging and certain manufacturing processes, may require a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) clearance or PMA in the first instance, but the FDA may review the manufacturer s decision. The FDA may not agree with a manufacturer s decision regarding whether a new clearance or approval is necessary for a modification, and may retroactively require the manufacturer to submit a premarket notification requesting 510(k) clearance or an application for PMA. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. No assurance can be given that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA. If the FDA requires us to cease marketing and recall the modified device until we obtain a new 510(k) clearance or PMA, our business, financial condition, operating results and future growth prospects could be materially adversely affected. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

Healthcare policy changes, including legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, substantially changes the way health care is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the medical device industry. The PPACA includes, among other things, the following measures:

- an excise tax on any entity that manufactures or imports medical devices offered for sale in the United States;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on device manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, beginning on or before January 1, 2013;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new licensure framework for follow-on biologic products.

We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, these provisions as adopted could meaningfully change the way healthcare is delivered and financed, and may materially impact numerous aspects of our business. In particular, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and operating results.

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In addition, in the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products, and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our financial position and operating results.

Furthermore, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in markets where we do business. We could experience a negative impact on our operating results due to increased pricing pressure in the United States and certain other markets. Governments, hospitals and other third-party payors could reduce the amount of approved reimbursements for our products. Reductions in reimbursement levels or coverage or other cost-containment measures could unfavorably affect our future operating results.

Our financial performance may be adversely affected by medical device tax provisions in the health care reform laws.

The PPACA imposes a deductible excise tax equal to 2.3% of the price of a medical device on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, beginning in 2013. Under these provisions, the total cost to the medical device industry is estimated to be approximately $20 billion over 10 years. These taxes would result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our operating results and our cash flows.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in improper promotion of our products.

Our currently marketed products have been cleared by the FDA s 510(k) clearance process for use under specific circumstances. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indication is known as off-label use. We cannot prevent a surgeon from using our products or procedure for off-label use, as the FDA does not restrict or regulate a physician s choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitute promotion of an off-label use, the FDA could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

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In addition, there may be increased risk of injury if surgeons attempt to use our products off-label. Furthermore, the use of our products for indications other than those indications for which our products have been cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients. Surgeons also may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert our management s attention and result in substantial damage awards against us. Any of these events could harm our business and operating results.

If our marketed medical devices are defective or otherwise pose safety risks, the FDA and similar foreign governmental authorities could require their recall, or we may initiate a recall of our products voluntarily.

The FDA and similar foreign governmental authorities may require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. In the past we have initiated voluntary product recalls. For example, in 2008, we recalled a small number of medical devices due to a mislabeled product. We requested FDA closure of the recall in January 2010. A government-mandated or voluntary recall by us or one of our sales agencies could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and operating results. Any recall could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. We also may be required to bear other costs or take other actions that may have a negative impact on our future revenue and our ability to generate profits. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our revenue. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In the EEA we must comply with the EU Medical Device Vigilance System, the purpose of which is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents must be reported to the competent authorities of the Member States of the EEA. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. Incidents are evaluated by the EEA competent authorities to whom they have been reported, and where appropriate, information is disseminated between them in the form of National Competent Authority Reports, or NCARs. The Medical Device Vigilance System is further intended to facilitate a direct, early and harmonized implementation of Field Safety Corrective Actions, or FSCAs across the Member States of the EEA where the device is in use. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

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If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, or MDR, we are required to report to the FDA any incident in which our product has or may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our manufacturing operations require us to comply with the FDA s and other governmental authorities laws and regulations regarding the manufacture and production of medical devices, which is costly and could subject us to enforcement action.

We and certain of our third-party manufacturers are required to comply with the FDA s Quality System Regulation, or QSR, which covers the methods of documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and certain of our suppliers also are subject to the regulations of foreign jurisdictions regarding the manufacturing process for our products marketed outside of the United States. The FDA enforces the QSR through periodic announced and unannounced inspections of manufacturing facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;
- withdrawing 510(k) clearances or PMAs that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these actions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. We also may be required to bear other costs or take other actions that may have a negative impact on our future revenue and our ability to generate profits. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

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We are subject to substantial post-market government regulation that could have a material adverse effect on our business.

The production and marketing of our products are subject to extensive regulation and review by the FDA and numerous other governmental authorities both in the United States and abroad. For example, in addition to other state regulatory requirements, Massachusetts, California and Arizona require compliance with the standards in industry codes such as the Code of Ethics on Interactions with Health Care Professionals issued by the Advanced Medical Technology Association (commonly known as AdvaMed), the Code on Interactions with Healthcare Professionals issued by MEDEC, the national association of Canada s medical technology companies, and international equivalents. The failure by us or one of our suppliers to comply with applicable regulatory requirements could result in, among other things, the FDA or other governmental authorities:

- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- delaying the introduction of our new products into the market;
- recalling or seizing our products;
- withdrawing, delaying or denying approvals or clearances for our products;
- issuing warning letters or untitled letters;
- imposing operating restrictions;
- imposing injunctions; and
- commencing criminal prosecutions.

Failure to comply with applicable regulatory requirements also could result in civil actions against us and other unanticipated expenditures. If any of these actions were to occur it would harm our reputation and cause our product revenue to suffer and may prevent us from generating revenue.

The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects.

Our ongoing research and development, pre-clinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting post-market clinical studies of some or our products to gather additional information about these products safety, efficacy or optimal use. In the future we may conduct clinical trials to support approval of new products. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical trials may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and studies. The clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our products and generate revenue. It is also possible that patients enrolled in clinical trials will experience adverse side effects

that are not currently part of the product s profile.

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If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

Future regulatory actions may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA and other regulations and guidance are often revised or reinterpreted in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

We may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid or other third-party payors for our products or the procedures in which our products are used, healthcare regulation by federal and state governments could significantly impact our business. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include:

- the federal Anti-Kickback Law, which constrains our marketing practices and those of our independent sales agencies, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration, intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs;

- federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information; and

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state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our past or present operations, or those of our independent sales agencies, are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal healthcare programs and the curtailment or restructuring of our operations. Similarly, if the healthcare providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our company being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

The PPACA also includes a number of provisions that impact medical device manufacturers, including new reporting and disclosure requirements on device and drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013. Such information will be made publicly available in a searchable format beginning September 30, 2013. In addition, device and drug manufacturers also will be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. The PPACA also imposes excise taxes on medical device manufacturers, permits the use of comparative effectiveness research to make Medicare coverage determinations in certain circumstances, creates an Independent Medicare Advisory Board charged with recommending ways to reduce the rate of Medicare spending and changes payment methodologies under the Medicare and Medicaid programs. All of these changes could adversely affect our business and financial results.

Governments and regulatory authorities have increased their enforcement of these healthcare fraud and abuse laws in recent years. For example, in 2007 five competitors in the orthopaedics industry settled a Department of Justice investigation into the financial relationships and consulting agreements between the companies and surgeons. The companies agreed to new corporate compliance procedures and federal monitoring. At issue were financial inducements designed to encourage physicians to use the payor company s products exclusively and the failure of physicians to disclose these relationships to hospitals and patients. Individual states also may be investigating the relationship between healthcare providers and companies in the orthopaedics industry. Many states have their own regulations governing the relationship between companies and healthcare providers. While we have not been the target of any investigations, we cannot guarantee that we will not be investigated in the future. If investigated we cannot assure that the costs of defending or resolving those investigations or proceedings would not have a material adverse effect on our financial condition, operating results and cash flows.

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Failure to obtain and maintain regulatory approvals in jurisdictions outside the United States will prevent us from marketing our products in such jurisdictions.

We currently market, and intend to continue to market, our products outside the United States. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA clearance or approval. The regulatory approval process outside the United States may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks. For example, in order to market our products in the Member States of the EEA, our devices are required to comply with the essential requirements of the EU Medical Devices Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, and Council Directive 90/385/EEC of 20 June 2009 relating to active implantable medical devices, as amended). Compliance with these requirements entitles us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directives, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up an EC Declaration of Conformity, which allows us to affix the CE mark to our products.

We may not obtain regulatory approvals or certifications outside the United States on a timely basis, if at all. Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities or Notified Bodies in other countries, and approval or certification by one foreign regulatory authority or Notified Body does not ensure approval by regulatory authorities in other countries or by the FDA. We may be required to perform additional pre-clinical or clinical studies even if FDA clearance or approval, or the right to bear the CE mark, has been obtained. If we fail to receive necessary approvals to commercialize our products in jurisdictions outside the United States on a timely basis, or at all, our business, financial condition and operating results could be adversely affected.

Our existing xenograft-based biologics business is and any future biologics products we pursue would be subject to emerging governmental regulations that could materially affect our business.

Some of our products are xenograft, or animal-based, tissue products. Our principal xenograft-based biologics offering is Conexa reconstructive tissue matrix. All of our current xenograft tissue-based products are regulated as medical devices and are subject to the FDA s medical device regulations.

We currently are planning to offer products based on human tissue. The FDA has statutory authority to regulate human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient, including allograft-based products. The FDA, EU and Health Canada have been working to establish more comprehensive regulatory frameworks for allograft-based, tissue-containing products, which are principally derived from cadaveric tissue.

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Section 361 of the Public Health Service Act, or PHSA, authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to: registering facilities and listing products with the FDA; screening and testing for tissue donor eligibility; Good Tissue Practice, or GTP, when processing, storing, labeling and distributing HCT/Ps, including required labeling information; stringent recordkeeping; and adverse event reporting. The FDA has also proposed extensive additional requirements that address sub-contracted tissue services, tracking to the recipient/patient, and donor records review. If a tissue-based product is considered human tissue, the FDA requirements focus on preventing the introduction, transmission and spread of communicable diseases to recipients. A product regulated solely as a 361 HCT/P is not required to undergo premarket clearance or approval.

The FDA may inspect facilities engaged in manufacturing 361 HCT/Ps and may issue untitled letters, warning letters, or otherwise authorize orders of retention, recall, destruction and cessation of manufacturing if the FDA has reasonable grounds to believe that an HCT/P or the facilities where it is manufactured are in violation of applicable regulations. There also are requirements relating to the import of HCT/Ps that allow the FDA to make a decision as to the HCT/Ps admissibility into the United States.

An HCT/P is eligible for regulation solely as a 361 HCT/P if it is: minimally manipulated; intended for homologous use as determined by labeling, advertising or other indications of the manufacturer s objective intent for a homologous use; the manufacture does not involve combination with another article, except for water, crystalloids or a sterilizing, preserving, or storage agent (not raising new clinical safety concerns for the HCT/P); and it does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function or, if it has such an effect, it is intended for autologous use or allogenetic use in close relatives or for reproductive use. If any of these requirements are not met, then the HCT/P is also subject to applicable biologic, device, or drug regulation under the FDCA or the PHSA. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics under the PHSA, or devices or drugs under the FDCA, including premarket licensure, clearance or approval.

Title VII of the PPACA, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates a new licensure framework for follow-on biologic products, which could ultimately subject our biologics business to competition to so-called biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a referenced, branded biologic product. Previously, there had been no licensure pathway for such a follow-on product. While we do not anticipate that the FDA will license a follow-on biologic for several years, given the need to generate data sufficient to demonstrate biosimilarity to or interchangeability with the branded biologic according to criteria set forth in the BPCIA, as well as the need for the FDA to implement the BPCIA s provisions with respect to particular classes of biologic products, we cannot guarantee that our biologics will not eventually become subject to direct competition by a licensed biosimilar.

Procurement of certain human organs and tissue for transplantation, including allograft tissue we may use in future products, is subject to federal regulation under the National Organ Transplant Act, or NOTA. NOTA prohibits the acquisition, receipt, or other transfer of certain human organs, including bone and other human tissue, for valuable consideration within the meaning of NOTA. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human organs. For any future products implicating NOTA s requirements, we would reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they would provide to us. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our services, thereby negatively impacting our future revenue and profitability. If we were to be found to have violated NOTA s prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our operating results. Further, in the future, if NOTA is amended or reinterpreted, we may not be able to pass these expenses on to our customers and, as a result, our business could be adversely affected.

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Our operations involve the use of hazardous materials, and we must comply with environmental health and safety laws and regulations, which can be expensive and may affect our business and operating results.

We are subject to a variety of laws and regulations of the countries in which we operate and distribute products, such as the European Union, or EU, France, Ireland, other European nations and the United States, relating to the use, registration, handling, storage, disposal, recycling and human exposure to hazardous materials. Liability under environmental laws can be joint and several and without regard to comparative fault, and environmental, health and safety laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could harm our business. In the EU, where our manufacturing facilities are located, we and our suppliers are subject to EU environmental requirements such as the Registration, Evaluation, Authorisation and Restriction of Chemicals, or REACH, regulation. In addition, we are subject to the environmental, health and safety requirements of individual European countries in which we operate such as France and Ireland. For example, in France, requirements known as the Installations Classées pour la Protection de l Environnement regime provide for specific environmental standards related to industrial operations such as noise, water treatment, air quality and energy consumption. In Ireland, our manufacturing facilities are likewise subject to local environmental regulations, such as related to water pollution and water quality, that are administered by the Environmental Protection Agency. We believe that we are in material compliance with all applicable environmental, health and safety requirements in the countries in which we operate and do not have reason to believe that we are responsible for any cleanup liabilities. In addition, certain hazardous materials are present at some of our facilities, such as asbestos, that we believe are managed in compliance with all applicable laws. We also are subject to greenhouse gas regulations in the EU and elsewhere and we believe that we are in compliance based on present emissions levels at our facilities. Although we believe that our activities conform in all material respects with applicable environmental, health and safety laws, we cannot assure you that violations of such laws will not arise as a result of human error, accident, equipment failure, presently unknown conditions or other causes. The failure to comply with past, present or future laws, including potential laws relating to climate control initiatives, could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations. In particular, in relation to our manufacturing facility located in Saint-Ismier, France, we require a formal agreement and/or authorization to discharge wastewater to the local community wastewater treatment system, or could be subject to fines, civil liability, and/or reduced throughput. As has been standard practice for business operations in the area, we believe that we obtained authorization from local authorities to connect to the wastewater discharge network at the time we first made our connection in 2003. When authority over such matters was assumed by an inter-community agency, the *Syndicat Intercommunal de la Zone Verte* (SIZOV), we applied for and received formal authorization as of October 28, 2010. We also expect that our operations will be affected by other new environmental and health and safety laws, including laws relating to climate control initiatives, on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they could result in additional costs and may require us to change how we design, manufacture or distribute our products, which could have a material adverse effect on our business.

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Our business is subject to evolving corporate governance and public disclosure regulations that have increased both our compliance costs and the risk of noncompliance, which could have an adverse effect on our stock price.

We are subject to changing rules and regulations promulgated by a number of governmental and self-regulated organizations, including the SEC, the NASDAQ Stock Market, and the FASB. These rules and regulations continue to evolve in scope and complexity and many new requirements have been created in response to laws enacted by Congress, making compliance more difficult and uncertain. For example, our efforts to comply with the Dodd-Frank Wall Street Reform and Consumer Protection Act and other new regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related to Our Intellectual Property

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors.

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. The patents we own may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes that are similar to ours. In addition, we cannot be certain that any of our pending patent applications will be issued. The USPTO may reject or require a significant narrowing of the claims in our pending patent applications affecting the patents issuing from such applications. Any patents issuing from the pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO and the proceedings may be time-consuming, which may cause significant diversion of effort by our technical and management personnel. These proceedings could result in adverse decisions as to the validity of our inventions and may result in the narrowing or cancellation of claims in issued patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as U.S. laws or at all. We also may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

In the event a competitor infringes our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could harm our business and operating results.

In addition, there are numerous recent changes to the U.S. patent laws and proposed changes to the rules of the USPTO, which may have a significant impact on our ability to obtain and enforce intellectual property rights. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was adopted in September 2011. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. Under the Leahy-Smith Act, the U.S. is transitioning from a first-to-invent system to a first-to-file system for patent applications filed on or after March 16, 2013. With respect to patent applications filed on or after March 16, 2013, if we are the first to invent but not the first to file a patent application, we may not be able to fully protect our intellectual property rights and may be found to

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have violated the intellectual property rights of others if we continue to operate in the absence of a patent issued to us. The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until up to 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks, or we may not have adequate resources to enforce our trademarks.

In addition, we hold licenses from third parties that are necessary to the design and manufacturing of some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business.

In addition to patents, we seek to protect our trade secrets, know-how and other unpatented technology, in part, with confidentiality agreements with our vendors, employees, consultants and others who may have access to proprietary information. We cannot be certain, however, that these agreements will not be breached, adequate remedies for any breach would be available or our trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors.

If we are subject to any future intellectual property lawsuits, a court could require us to pay significant damages or prevent us from selling our products.

The orthopaedic medical device industry is litigious with respect to patents and other intellectual property rights. Companies in the orthopaedic medical device industry have used intellectual property litigation to gain a competitive advantage. In the future, we may become a party to lawsuits involving patents or other intellectual property. A legal proceeding, regardless of outcome, could drain our financial resources and divert the time and effort of our management. A patent infringement suit or other infringement or misappropriation claim brought against us or any of our licensees may force us or any of our licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or any licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we or our licensees were able to obtain rights to the third party s intellectual property, these rights may be nonexclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

In any infringement lawsuit, a third party could seek to enjoin, or prevent, us from commercializing our existing or future products, or may seek damages from us, and any such lawsuit would likely be expensive for us to defend against. If we lose one of these proceedings, a court or a

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similar foreign governing body could require us to pay significant damages to third parties, seek licenses from third parties, pay ongoing royalties, redesign our products so that they do not infringe or prevent us from manufacturing, using or selling our products. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

From time to time, in the ordinary course of business, we receive notices from third parties alleging infringement or misappropriation of the patent, trademark or other intellectual property rights of third parties by us or our customers in connection with the use of our products or we otherwise may become aware of possible infringement claims against us. We routinely analyze such claims and determine how best to respond in light of the circumstances existing at the time, including the importance of the intellectual property right to us and the third party, the relative strength of our position of non-infringement or non-misappropriation and the product or products incorporating the intellectual property right at issue.

Risks Relating to Our Ordinary Shares and this Offering

The trading volume and prices of our ordinary shares have been and may continue to be volatile, which could result in substantial losses to our shareholders.

The trading volume and prices of our ordinary shares have been and may continue to be volatile and could fluctuate widely due to factors beyond our control. Since our initial public offering in February 2011, the sale price of our ordinary shares has ranged from $16.69 per share to $29.93 per share, as reported by the NASDAQ Global Select Market. This may happen because of broad market and industry factors, like the performance and fluctuation of the market prices of other companies with business operations located mainly in Europe that have listed their securities in the United States. In addition to market and industry factors, the price and trading volume for our ordinary shares may be highly volatile for factors specific to our own operations, including the following:

- variations in our revenue, earnings and cash flow;
- announcements of new investments, acquisitions, strategic partnerships or joint ventures;
- announcements of new services and expansions by us or our competitors;
- changes in financial estimates by securities analysts;
- additions or departures of key personnel;
- sales of our equity securities by our significant shareholders or management or sales of additional equity securities by our company;
- potential litigation or regulatory investigations; and
- fluctuations in market prices for our products.

Any of these factors may result in large and sudden changes in the volume and price at which our ordinary shares trade. In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company s securities. If we were involved in a class action suit, it could divert a significant amount of our management s attention and other resources from our business and operations, which could harm our operating results and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect

on our financial condition and operating results.

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We have in the past and may in the future experience deficiencies, including material weaknesses, in our internal control over financial reporting. Our business and our share price may be adversely affected if we do not remediate these material weaknesses or if we have other weaknesses in our internal controls.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. A material weakness, as defined in the standards established by the Public Company Accounting Oversight Board, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for fiscal 2009, we identified a material weakness in our internal control over financial reporting relating to our audited financial statements for fiscal 2007 and fiscal 2008. Specifically, in our case, management and our independent registered accounting firm determined that internal controls over identifying, evaluating and documenting accounting analysis and conclusions over complex non-routine transactions, including related-party transactions, required strengthening. Although we remediated this material weakness, additional control deficiencies may be identified by management or our independent registered public accounting firm, and such control deficiencies also could represent one or more material weaknesses. A report by us of a material weakness may cause investors to lose confidence in our financial statements, and the trading price of our ordinary shares may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our ordinary shares may decline.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our ordinary shares, the market price for our ordinary shares and trading volume could decline.

The trading market for our ordinary shares is influenced by research or reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our ordinary shares, the market price for our ordinary shares likely would decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our ordinary shares to decline.

The sale or availability for sale of substantial amounts of our ordinary shares could adversely affect their market price.

Sales of substantial amounts of our ordinary shares in the public market, or the perception that these sales could occur, could adversely affect the market price of our ordinary shares and could materially impair our ability to raise capital through equity offerings in the future. We cannot predict what effect, if any, market sales of securities held by our significant shareholders, the selling shareholders or any other shareholder or the availability of these securities for future sale will have on the market price of our ordinary shares.

We are party to a registration rights agreement with certain of our shareholders and officers, including TMG Holdings Coöperatief U.A., or TMG, Vertical Fund I, L.P., Vertical Fund II, L.P., entities affiliated with Alain Tornier, Douglas W. Kohrs and certain selling shareholders in this offering, which requires us to register ordinary shares held by these persons under the Securities Act, subject to certain limitations, restrictions and conditions. The market price of our ordinary shares could decline as a result of the registration and sale of or the perception that registration and sales may occur of a large number of our ordinary shares.

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We are a Netherlands company, and it may be difficult for you to obtain or enforce judgments against us or our executive officers, some of our directors and some of our named experts in the United States.

We were formed under the laws of the Netherlands and, as such, the rights of holders of our ordinary shares and the civil liability of our directors are governed by Dutch laws and our amended articles of association. The rights of shareholders under the laws of the Netherlands may differ from the rights of shareholders of companies incorporated in other jurisdictions. Some of the named experts referred to in this registration statement are not residents of the United States, and certain of our directors and executive officers and most of our assets and some of the assets of our directors are located outside the United States. As a result, you may not be able to serve process on us or on such persons in the United States or obtain or enforce judgments from U.S. courts against them or us based on the civil liability provisions of the securities laws of the United States. There is doubt as to whether Dutch courts would enforce certain civil liabilities under U.S. securities laws in original actions or enforce claims for punitive damages.

Under our amended articles of association, we indemnify and hold our directors harmless against all claims and suits brought against them, subject to limited exceptions. Although there is doubt as to whether U.S. courts would enforce such provision in an action brought in the United States under U.S. securities laws, such provision could make enforcing judgments obtained outside of the Netherlands more difficult to enforce against our assets in the Netherlands or jurisdictions that would apply Dutch law.

Rights of a holder of ordinary shares are governed by Dutch law and differ from the rights of shareholders under U.S. law.

We are a public limited liability company incorporated under Dutch law. The rights of holders of ordinary shares are governed by Dutch law and our amended articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. For example, Dutch law significantly limits the circumstances under which shareholders of Dutch companies may bring an action on behalf of a company.

We do not anticipate paying dividends on our ordinary shares.

We have not previously declared or paid cash dividends and we have no plan to declare or pay any dividends in the near future on our ordinary shares. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

Warburg Pincus (Bermuda) Private Equity IX, L.P. and its affiliates control approximately 44% of our ordinary shares, and this concentration of ownership may have an effect on transactions that are otherwise favorable to our shareholders.

Warburg Pincus (Bermuda) Private Equity IX, L.P. and its affiliates, or Warburg Pincus, beneficially own, in the aggregate, approximately 44% of our outstanding ordinary shares. These shareholders could have an effect on matters requiring our shareholders approval, including the election of directors. This concentration of ownership also may delay, deter or prevent a change in control, and

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may make some transactions more difficult or impossible to complete without the support of these shareholders, regardless of the impact of this transaction on our other shareholders. In addition, our securityholders agreement, as amended on August 27, 2010, gives TMG, an affiliate of Warburg Pincus, the right to designate three of the eight directors to be nominated to our board of directors for so long as TMG beneficially owns at least 25% of the outstanding shares, two of the eight directors for so long as TMG beneficially owns at least 10% but less than 25% of the outstanding shares and one of the eight directors for so long as TMG beneficially owns at least 5% but less than 10% of the outstanding shares, and we have agreed to use our reasonable best efforts to cause the TMG designees to be elected.

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USE OF PROCEEDS

All ordinary shares offered under this prospectus are being registered for the account of the selling shareholders. We will not receive any of the proceeds from the sale of ordinary shares offered under this prospectus by the selling shareholders. This offering is intended to satisfy our obligations to register under the Securities Act the resale of the ordinary shares that we issued to the selling shareholders at the closing of our acquisition of OrthoHelix.

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SELLING SHAREHOLDERS

The ordinary shares offered under this prospectus may be offered from time to time by the selling shareholders named below or by any of their pledges, donees, transferees or other successors in interest. As used in this prospectus, the term selling shareholder includes those selling shareholders identified below and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling shareholder as a gift, pledge or other non-sale related transfer. All of the selling shareholders named below acquired the ordinary shares being offered under this prospectus directly from us at the closing of our acquisition of OrthoHelix on October 4, 2012. In connection with the acquisition of OrthoHelix, we granted certain registration rights to the selling shareholders covering the ordinary shares they received in the acquisition. In connection with such registration rights, we filed with the SEC a shelf registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale or other disposition of the ordinary shares offered by this prospectus from time to time, in privately negotiated transactions or otherwise. We also have agreed to prepare and file amendments and supplements to the shelf registration statement to the extent necessary to keep the registration statement effective for the period of time required under the merger agreement.

The following table sets forth as of October 15, 2012: (1) the name of each selling shareholder for whom we are registering ordinary shares under this registration statement, (2) the number of ordinary shares beneficially owned by each of the selling shareholders prior to the offering, determined in accordance with Rule 13d-3 under the Exchange Act, (3) the number of ordinary shares that may be offered by each selling shareholder under this prospectus and (4) the number of ordinary shares to be owned by each selling shareholder after completion of this offering. The table assumes that the selling shareholders will sell all of the shares offered by them in this offering. However, we are unable to determine the exact number of shares that actually will be sold or when or if these sales will occur. We will not receive any of the proceeds from the sale of the shares offered under this prospectus. The amounts and information set forth below are based upon information provided to us by the selling shareholders or his, her or its representative, or on our records, as of October 15, 2012. The percentage of beneficial ownership for the following table is based on 41,718,896 ordinary shares outstanding as of October 15, 2012.

To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all ordinary shares shown in the table to be beneficially owned by such person. Except as set described below, none of the selling shareholders has had any position, office or other material relationship with us or any of our predecessors or affiliates within the past three years. Information concerning the selling shareholders may change from time to time, and any changed information will be set forth in supplements to this prospectus to the extent required.

	Shares Beneficially Owned Prior to the Offering		Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering	
Selling Shareholder	**Number**	**Percentage**	**Offered**	**Number**	**Percentage**
Alliance Medical, LLC[1]	237	*	237	0	
Bauer, Richard	1,606	*	1,606	0	
Belap Management Ltd. Co.[2]	963	*	963	0	
Bell, Robert H.	14,417	*	14,417	0	
Bennett, Gordon	1,307	*	1,307	0	
Biondi, John	950	*	950	0	
Bluewater Management Co, LLC[3]	402	*	402	0	
Boyer, Martin I.	356	*	356	0	

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Selling Shareholder	Shares Beneficially Owned Prior to the Offering Number	Percentage	Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering Number	Percentage
Britton, Eric	803	*	803	0	
Brown, Tracy	6,479	*	6,479	0	
Brubaker, H. Patricia	3,375	*	3,375	0	
Brudney, Robert	1,462	*	1,462	0	
Bucci, Bart	11,228	*	11,228	0	
Cadogan, William	98,255	*	98,255	0	
Conway Private Equity Group, LLC[4]	7,438	*	7,438	0	
Coon, Steven	1,981	*	1,981	0	
CT Partners Executive Search, Inc.[5]	12,848	*	12,848	0	
DB Kay Designs, Inc.[6]	83,328	*	83,328	0	
Delamarter, Rick	6,820	*	6,820	0	
Den Hartog, Bryan D.	80,486	*	80,486	0	
Den Hartog Family Remainder Unitrust, U.S. Bank Trust Nat. Ass. SD.[7]	14,262	*	14,262	0	
Dickenson II MPP, David S.[8]	3,071	*	3,071	0	
Dietrich, John	475	*	475	0	
Ellis, Gary	21,107	*	21,107	0	
Engles, Drew	594	*	594	0	
Fairey, Laurence	2,852	*	2,852	0	
Friscia, David A.	7,483	*	7,483	0	
Gansand Partners Limited Liability Company[9]	1,864	*	1,864	0	
Grossman, Charles L.	3,219	*	3,219	0	
Hoskins, Brett	2,268	*	2,268	0	
Huston, John O. (TTE)	803	*	803	0	
Isaacs, Vernon	10,078	*	10,078	0	
James F. Kirk Family Trust[10]	950	*	950	0	
Jeffrey E. Johnson, TOD Johnson Living Trust d/t 9/19/01[11]	39,960	*	39,960	0	
John M. Saada Jr. Declaration of Trust, dated July 12, 1998[12]	1,704	*	1,704	0	
John W. Dietrich Revocable Trust, amended 11/16/2007[13]	63,273	*	63,273	0	
Johnson, Jeffrey	356	*	356	0	
Kakarala, Nandini R.	2,377	*	2,377	0	
Kay, Albert	16,995	*	16,995	0	
Kay, David B.	15,213	*	15,213	0	
Kay, Mahala	950	*	950	0	
Kay, Mara E.	16,995	*	16,995	0	
Kelly Cohen, Meghan	475	*	475	0	
KJAAK Investments LP[14]	7,387	*	7,387	0	
Kohl, Stewart A.	8,782	*	8,782	0	
KPLML Family Ltd. Partnership[15]	402	*	402	0	
Ladd, Amy	499	*	499	0	
Leversedge, Fraser J.	4,256	*	4,256	0	
Martin I. Boyer Revocable Trust dated 11/12/2002[16]	5,823	*	5,823	0	
McCue, R. William	16,744	*	16,744	0	
McGlamry, Michael C.	190	*	190	0	
Montross, William G.	1,901	*	1,901	0	
Morris, Jay	2,360	*	2,360	0	
Morris, William H.	10,622	*	10,622	0	
Mullin, Patrick S.	805	*	805	0	
Munden, Frederick	6,180	*	6,180	0	
Murray, Victoria	2,377	*	2,377	0	
Mutual Capital Partners Fund I, L.P.[17]	307,583	*	307,583	0	

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Selling Shareholder	Shares Beneficially Owned Prior to the Offering Number	Percentage	Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering Number	Percentage
Myerson, Mark	35,841	*	35,841	0	
Neufeld, Steven	1,468	*	1,468	0	
Noblitt, Niles	2,852	*	2,852	0	
Philbin, Terrence M.	2,520	*	2,520	0	
Quill, George	4,422	*	4,422	0	
Richard L. Kovach Declaration of Trust u/a/d 9/2/05[18]	16,694	*	16,694	0	
Richardson Bryan Ramey	950	*	950	0	
River Cities Capital Fund IV L.P.[19]	524,795	1.3%	524,795	0	
River Cities Capital Fund IV (N.Q.P.) L.P.[20]	56,051	*	56,051	0	
Rubino, Cameron	9,650	*	9,650	0	
Sacajo Investments LLC[21]	46,508	*	46,508	0	
Sachar, Kulvinder	8,085	*	8,085	0	
Scioli, Mark	56,067	*	56,067	0	
Seiler III, John G.	190	*	190	0	
Sferra, James J.	142	*	142	0	
Shall, Lawrence	4,244	*	4,244	0	
Shelley L. and Cameron C. Rubino Family Trust[22]	11,802	*	11,802	0	
Shunk, Laura	15,236	*	15,236	0	
Slater, Thomas	998	*	998	0	
Smith, R. Clayton	484	*	484	0	
Spencer, John Jr.	2,944	*	2,944	0	
Square One Bank[23]	5,106	*	5,106	0	
Steven L. Haddad Trust U/A dated 5/19/04[24]	8,783	*	8,783	0	
Stripe, Dennis	90,628	*	90,628	0	
Symon Medical LLC[25]	682	*	682	0	
Synogen, Inc.[26]	41,683	*	41,683	0	
Tewari, Elena Bullani	2,377	*	2,377	0	
Thomas, Don	6,169	*	6,169	0	
Thordarson, David B.	19,147	*	19,147	0	
Tisza, Dennis	1,140	*	1,140	0	
Vaughan Medical, Inc.[27]	1,616	*	1,616	0	
Weil, Lowell	15,139	*	15,139	0	
Wilcox, Doug	950	*	950	0	
Zelman, Daniel N.	7,931	*	7,931	0	
TOTAL	1,941,270				

* Less than one percent (1%)

(1) Jessica Kern and Paul Kern have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Alliance Medical, LLC.

(2) Patrick S. Mullin, Managing Member of Belap Management Ltd. Co., has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Belap Management Ltd. Co.

(3) Kenneth A. Wakeen and Ann Marie Wakeen have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Bluewater Management Co, LLC.

(4) E. Timothy Holzheimon, and Joseph K. Justen, Esq., Co-Managers of Conway Private Equity Group, LLC, have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Conway Private Equity Group, LLC.

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(5) David C. Nocifora, Chief Operating Officer and Chief Financial Officer of CT Partners Executive Search, Inc. has sole voting and investment control with respect to our ordinary shares registered hereby for the account of CT Partners Executive Search, Inc.

(6) David B. Kay has sole voting and investment control with respect to our ordinary shares registered hereby for the account of DB Kay Designs, LLC.

(7) Jeffrey G. Denison, Trustee of the Den Hartog Family Remainder Unitrust, U.S. Bank Trust Nat. Ass. SD, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of the Den Hartog Family Remainder Unitrust, U.S. Bank Trust Nat. Ass. SD.

(8) David S. Dickenson II, Trustee of the David S. Dickenson II MPP, has sole voting and investment control with respect to our ordinary shares registered for the account of David S. Dickenson II MPP.

(9) Lyle G. Ganske and Drew Forhan have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Gansand Partners, LLC.

(10) James F. Kirk, Trustee of James F. Kirk Family Trust, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of James F. Kirk Family Trust.

(11) Jeffrey E. Johnson and Nancy R. Johnson, Trustees of Jeffrey E. Johnson, TOD Johnson Living Trust d/t 9/19/01, have sole voting and investment control with respect to our ordinary shares registered hereby for the account of the Jeffrey E. Johnson, TOD Johnson Living Trust d/t 9/19/01.

(12) John M. Saada, Trustee of the John M. Saada Jr. Declaration of Trust, dated July 12, 1998, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of the John M. Saada Jr. Declaration of Trust, dated July 12, 1998.

(13) John W. Dietrich, Trustee of the John W. Dietrich Revocable Trust, amended 11/16/2007, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of John W. Dietrich Revocable Trust, amended 11/16/2007.

(14) Kenneth Stephenson, President of KJAAK Investments LP, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of KJAAK Investment LP.

(15) Paul J. Schlather, General Partner of KPLML Family Ltd. Partnership, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of KPLML Family Ltd. Partnership.

(16) Martin I. Boyer, Trustee of Martin I. Boyer Revocable Trust dated 11/12/2002, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Martin I. Boyer Revocable Trust dated 11/12/2002.

(17) Wayne H. Wallace and William S. Trainor have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Mutual Capital Partners Fund I, L.P.

(18) Richard L. Kovach, Trustee of Richard L. Kovach Declaration of Trust u/a/d 9/2/05, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Richard L. Kovach Declaration of Trust u/a/d 9/2/05.

(19) Daniel T. Fleming, J. Carter McNabb and Edwin T. Robinson, Managers of River Cities Management IV, LLC, General Partner of Capital Fund IV L.P., have sole voting and investment control with respect to our ordinary shares registered hereby for the account of River Cities Capital Fund IV L.P.

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(20) Daniel T. Fleming, J. Carter McNabb and Edwin T. Robinson, Managers of River Cities Management IV, LLC, General Partner of River Cities Capital Fund IV (N.Q.P.) L.P., have sole voting and investment control with respect to our ordinary shares registered hereby for the account of River Cities Capital Fund IV (N.Q.P.) L.P.

(21) Nancy Noblitt and Niles Noblitt, Initial Members of Sacajo Investments LLC, have sole voting and investment control with respect to our ordinary shares registered hereby for the account of Sacajo Investments LLC.

(22) Cameron C. Rubino and Shelly L. Rubino, Trustees of the Shelley L. and Cameron C. Rubino Family Trust, have sole voting and investment control with respect to our ordinary shares registered hereby for the account of the Shelley L. and Cameron C. Rubino Family Trust.

(23) Geoff Imboden, SVP/Treasurer of Square One Bank, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Square One Bank.

(24) Steven L. Haddad, Trustee of the Steven L. Haddad Trust U/A dated 5/19/04, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Steven L. Haddad Trust U/A dated 5/19/04.

(25) Eric Ottoson, Co-Principal of Symon Medical LLC, has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Symon Medical LLC.

(26) Richard R. Allen, President of Synogen, Inc., has sole voting and investment control with respect to our ordinary shares registered hereby for the account of Synogen, Inc.

(27) Kevin Vaughan, President of Vaughan Medical, Inc., has sole voting and investment control with respect to Vaughan Medical, Inc.

Material Relationships Between Selling Shareholders and Tornier

As described above, each of the selling shareholders are former stockholders, option holders or warrant holders of OrthoHelix and acquired the ordinary shares being offered under this prospectus at the closing of our acquisition of OrthoHelix on October 4, 2012. Under the terms of the merger agreement, we may be obligated to make additional earnout payments to the former stockholders, option holders and warrant holders of OrthoHelix of up to an aggregate of $20 million in cash based upon sales of Tornier s lower extremity joints and trauma products during fiscal years 2013 and 2014. Any earnout payments will be subject to certain rights of set-off for any post-closing indemnification obligations of OrthoHelix s former equity holders.

The following selling shareholders are current or former employees, or entities affiliated with current or former employees, of OrthoHelix: Dennis Stripe, Cameron Rubino, Shelley L. and Cameron C. Rubino Family Trust, Frederick Mundun, Tracy Brown, Dennis Tisza, Don Thomas and Meghan Kelly Cohen. Some of these employees have employment agreements with OrthoHelix.

The following selling shareholders are former directors, or entities affiliated with former directors, of OrthoHelix: DBKay Designs, LLC, David B. Kay, Dennis Stripe, William Cadogan, Mutual Capital Partners Fund I, L.P.

The following selling shareholders are current or former consultants, or entities affiliated with current or former consultants, of OrthoHelix: Mark Scioli, R. Bryan D. Den Hartog, Den Hartog Family Remainder Unitrust, U.S. Bank Trust Nat. Ass. SD, Jeffrey E. Johnson, TOD Johnson Lv Trust d/t 9/19/01, Jeffrey Johnson, Gordon Bennett, Fraser J. Leversedge, Drew Engles, John G. Seiler, Steven L.

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Haddad Trust U/A 5/19/04, Lowell Weil, Gansand Partners, LLC, Brett Hoskins, Alliance Medical, LLC, Jay Morris, Mark W. Scioli, John Dietrich, John W. Dietrich Revocable Trust, amended 11/16/2007, Martin I. Boyer, Martin I. Boyer revocable trust dated 11/12/2002, William G. Montross, Mark Myerson, David B. Thordarson, David A. Friscia, George Quill, Amy Ladd, Terrence M. Philbin, Square One Bank, Gansand Partners, LLC, John M. Saada Jr. Declaration of Trust dated July 12, 1998, James J. Sferra and Laura F. Shunk.

The following selling shareholders are current employees or consultants, or entities affiliated with current employees or consultants, of Tornier or one of our subsidiaries: Dennis Stripe, Cameron Rubino, Dean Banks, Tracy Brown, David Kay, M.D., Shelley L. and Cameron C. Rubino Family Trust, Jay Morris, Brett Hoskins, Symon Medical LLC, Mark Myerson, Lowell Weil and Steven Neufeld.

The following selling shareholders have entered into lock-up and leak-out agreements with us pursuant to which such shareholders have agreed not to sell, offer to sell, contract to sell, pledge or otherwise transfer or dispose of, directly or indirectly, the ordinary shares that such shareholders received in connection with our acquisition of OrthoHelix until on or after February 1, 2013; provided, however, that beginning on November 5, 2013 and on each trading day thereafter, a portion of each such shareholder s shares will no longer be subject to such transfer restrictions: DBKay Designs, Inc., Albert Kay, David Kay, Mara E. Kay, Mahala Kay, Gary Ellis, Shelley L. and Cameron C. Rubino Family Trust, Cameron Rubino, Sacajo Investments LLC, Richard L. Kovach Declaration of Trust u/a/d 9/2/05, Mutual Capital Partners Fund I, L.P., William Cadogan, John W. Dietrich Revocable Trust, amended 11/16/2007, Mark Scioli, Bryan D. DenHartog, DenHartog Family Remainder Unitrust, U.S. Bank Trust Nat. Ass. SD, David B. Thordarson, Mark Myerson, Dennis Stripe, River Cities Capital Fund IV L.P. and River Cities Capital Fund IV (N.Q.P.). In addition, such selling shareholders also agreed, if reasonably requested by us and an underwriter of our equity securities engaged by us, and so long as such shareholders hold 500,000 or more of our ordinary shares in the aggregate, to enter into an additional similar agreement regarding restrictions on transfer of the ordinary shares they acquired in connection with our acquisition of OrthoHelix for that period of time as reasonably requested by the underwriter. In exchange for such agreement, we agreed to provide such selling shareholders piggyback registration rights under our existing registration rights agreement dated as of July 16, 2010 by and among the parties thereto and us, and if requested by such selling shareholders, to include in any such registration at least $20 million in ordinary shares held by such selling shareholders.

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PLAN OF DISTRIBUTION

The selling shareholders and any of their respective transferees, pledgees, donees, assignees or other successors-in-interest may, from time to time, sell any or all their respective ordinary shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions, subject to certain transfer restrictions imposed upon certain of the shares of common stock covered by this prospectus. See Selling Shareholders. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling shareholders 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 or market distribution in accordance with the rules of the applicable exchange or market;
- 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 shareholders to sell a specified number of such shares at a stipulated price per share;
- through options, swaps or derivatives;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling shareholders also may sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

In effecting sales, broker-dealers or agents engaged by the selling shareholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling shareholders in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the selling shareholders and any broker-dealers who execute sales for the selling shareholders may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such case, any profits realized by the selling shareholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed the amount permitted by applicable regulations.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

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The selling shareholders have informed us that none of them has any agreement or understanding, directly or indirectly, with any person to distribute the ordinary shares. If any selling shareholder notifies us that an arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering or secondary distribution or a purchase by a broker or dealer, we may be required to file a prospectus supplement pursuant to the applicable rules promulgated under the Securities Act.

We have advised the selling shareholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling shareholders and their affiliates. In addition, we will make copies of this prospectus available to the selling shareholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling shareholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Certain of the selling shareholders have entered into lock-up and leak-out agreements with us pursuant to which such shareholders have agreed not to sell, offer to sell, contract to sell, pledge or otherwise transfer or dispose of, directly or indirectly, the ordinary shares that such shareholders received in connection with our acquisition of OrthoHelix until on or after February 1, 2013; provided, however, that beginning on November 5, 2013 and on each trading day thereafter, a portion of each such shareholder s shares will no longer be subject to such transfer restrictions.

We agreed to keep the registration statement of which this prospectus is a part effective until at least October 4, 2013. The selling shareholders will pay any underwriting discounts and commissions and expenses incurred by the selling shareholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling shareholders in disposing of the shares. We will bear all other reasonable costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, all national securities exchange or automated quotation system application and filing fees, blue sky registration and filing fees, and fees and expenses of our counsel and our accountants.

LEGAL MATTERS

The validity of the ordinary shares being offered by this prospectus has been passed upon for us by Stibbe N.V., Amsterdam, the Netherlands.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended January 1, 2012, and the effectiveness of our internal control over financial reporting as of January 1, 2012, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule and our management s assessment of the effectiveness of internal control over financial reporting as of January 1, 2012 are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

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WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we file annual, quarterly and special reports, proxy statements and other information with the SEC relating to our business, financial results and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the SEC s Public Reference Room and via the SEC s website (see below for more information).

In connection with the ordinary shares offered by this prospectus, we have filed a registration statement on Form S-3 under the Securities Act with the SEC. This prospectus, which constitutes a part of that registration statement, does not contain all of the information included in that registration statement and its accompanying exhibits and schedules. For further information with respect to our ordinary shares and us you should refer to that registration statement and its accompanying exhibits and schedules.

You may inspect a copy of the registration statement of which this prospectus is a part and its accompanying exhibits and schedules, as well as the reports, proxy statements and other information we file with the SEC, without charge at the SEC s Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and you may obtain copies of all or any part of the registration statement from those offices for a fee. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically, including us. The address of the site is *http://www.sec.gov*.

In addition, we maintain a website that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our website is *www.tornier.com*. Our website, and the information contained on that site, or connected to that site, are not intended to be part of this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information contained in the documents we file with the SEC, 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, and later information that we file with the SEC will update and supersede this information. We are incorporating by reference the following documents into this prospectus:

- our annual report on Form 10-K for the year ended January 1, 2012;
- our quarterly reports on Form 10-Q for the quarters ended April 1, 2012 and July 1, 2012;
- our current reports on Form 8-K filed on April 13, 2012, May 15, 2012, June 29, 2012, July 18, 2012, August 24, 2012, October 4, 2012 and October 17, 2012; and
- the description of our ordinary shares contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

We also are incorporating by reference into this prospectus any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of the registration statement of which this prospectus and prior to the termination of the offering of the securities to which this prospectus relates. In no event, however, will any of the information that we furnish to the SEC in any current report on Form 8-K or any other report or filing be incorporated by reference into,

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

We will provide without charge to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon written or oral request of such person, a copy of any or all of the documents incorporated by reference in this prospectus, other than exhibits to such documents unless such exhibits are specifically incorporated by reference into such documents. Requests may be made in writing to: Tornier N.V., Fred. Roeskestraat 123, 1076 EE Amsterdam, The Netherlands, or by telephone at (+ 31) 20 675 4002, or by email at kklemz@tornier.com.

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1,941,270 Shares

Ordinary Shares

PROSPECTUS

, 2012

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses payable by Tornier in connection with the issuance and distribution of the ordinary shares being registered. All such expenses are estimated except for the SEC registration fee.

SEC registration fee	$ 5,007
Fees and expenses of legal counsel for Tornier	15,000
Fees and expenses of accountants for Tornier	10,000
Miscellaneous	5,000
*Total	$ 35,007

* None of the expenses listed above will be borne by the selling shareholders.

Item 15. Indemnification of Directors and Officers

Our articles of association provide that we shall indemnify any of our directors against all adverse financial effects incurred by such person in connection with any action, suit or proceeding if such person acted in good faith and in a manner that reasonably could be believed to be in or not opposed to our best interests. In addition, we have entered into indemnification agreements with our directors and officers.

Each indemnification agreement, which is governed by the laws of the State of Delaware (USA), provide, among other things, for indemnification to the fullest extent permitted by law and our articles of association against any and all expenses (including attorneys fees) and liabilities, judgments, fines and amounts paid in settlement actually and reasonably incurred by a director or officer or on such director s or officer s behalf in connection with such action, suit or proceeding and any appeal therefrom, but shall only be provided if the director or officer acted in good faith and in a manner such director or officer reasonably believed to be in or not opposed to the best interests of our company, and, with respect to any criminal action, suit or proceeding, had no reasonable cause to believe such director s or officer s conduct was unlawful. Each indemnification agreement provides that the director or officer shall not be indemnified and advanced expenses (i) with respect to an action, suit or proceeding initiated by the director or officer unless so authorized by the board of directors of our company or (ii) with respect to any action, suit or proceeding instituted by the director or officer to enforce or interpret such indemnification agreement unless the director or officer is successful in establishing a right to indemnification in such action, suit or proceeding, in whole or in part, or unless and to the extent that the court in such action, suit or proceeding shall determine that, despite such director s or officer s failure to establish the right to indemnification, the director or officer is entitled to indemnity for such expenses.

We currently maintain liability insurance for our directors and officers. Such insurance would be available to our directors and officers in accordance with its terms.

Insofar as indemnification for liabilities arising under the Securities Act that may be permitted to directors and officers pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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Item 16. Exhibits

See Exhibit Index which is incorporated herein by reference.

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 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 a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(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 paragraphs (1)(i), (1)(ii) and (1)(iii) shall not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 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.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the

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Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; 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 effective date, 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 effective date.

(5) 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.

(6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the 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 Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of 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 Bloomington, State of Minnesota on October 17, 2012.

TORNIER N.V.

By /s/ Douglas W. Kohrs
Douglas W. Kohrs

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated, on the dates indicated below.

Name and Signature	Title	Date
/s/ Douglas W. Kohrs	President, Chief Executive Officer and Director	October 17, 2012
Douglas W. Kohrs	(principal executive officer)	
/s/ Shawn T McCormick	Chief Financial Officer	October 17, 2012
Shawn T McCormick	(principal financial and accounting officer)	
/s/ Sean D. Carney	Chairman of the Board	October 17, 2012
Sean D. Carney		
/s/ Richard B. Emmitt	Director	October 17, 2012
Richard B. Emmitt		
/s/ Pascal E.R. Girin	Director	October 17, 2012
Pascal E.R. Girin		
/s/ Kevin C. O Boyle	Director	October 17, 2012
Kevin C. O Boyle		
/s/ Alain Tornier	Director	October 17, 2012
Alain Tornier		
/s/ Richard F. Wallman	Director	October 17, 2012
Richard F. Wallman		

/s/ Elizabeth H. Weatherman	Director	October 17, 2012
Elizabeth H. Weatherman		

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TORNIER N.V.

REGISTRATION STATEMENT ON FORM S-3

EXHIBIT INDEX

Exhibit No.	Exhibit	Method of Filing
2.1	Agreement and Plan of Merger dated as of August 23, 2012 by and among Tornier N.V., Oscar Acquisition Corp., OrthoHelix Surgical Designs, Inc. and the Representative*	Incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 24, 2012 (File No. 001-35065)
4.1	Articles of Association of Tornier N.V.	Incorporated by reference to Exhibit 3.1 to the Registrant s Annual Report on Form 10-K for the fiscal year ended January 2, 2011 (File No. 001-35065)
4.2	Registrant s Specimen Certificate for Ordinary Shares	Incorporated by reference to Exhibit 4.1 to the Registrant s Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 14, 2010 (Registration No. 333-167370)
4.3	Registration Rights Agreement, dated July 16, 2010, by and among the investors on Schedule I thereto, the persons listed on Schedule II thereto and Tornier B.V.	Incorporated by reference to Exhibit 4.2 to the Registrant s Amendment No. 2 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 11, 2010 (Registration No. 333-167370)
4.4	Amendment and Waiver to Registration Rights Agreement, dated as of July 16, 2010, by and among the Investors and Tornier N.V.	Filed herewith
4.5	Form of Lock-Up and Leak-Out Agreement between certain holders and Tornier N.V.	Filed herewith
5.1	Opinion of Stibbe N.V.	Filed herewith
23.1	Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm	Filed herewith
23.2	Consent of Stibbe N.V.	Included in Exhibit 5.1
24.1	Power of Attorney	Filed herewith

* All exhibits and schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Tornier will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.