

Tornier N.V.
Form 10-K
March 14, 2011

Use these links to rapidly review the document

[Table of Contents](#)

[Item 8. Financial Statements and Supplementary Data.](#)

[Table of Contents](#)

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

FORM 10-K

(Mark
One)

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

For the fiscal year ended January 2, 2011

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission file number: 333-167370

TORNIER N.V.

(Exact name of registrant as specified in its charter)

The Netherlands
(State or other jurisdiction
of incorporation or organization)

98-0509600
(I.R.S. Employer
Identification No.)

Fred Roeskestraat 123
1076 EE Amsterdam, The Netherlands
(Address of principal executive offices)

None
(Zip Code)

Registrant's telephone number, including area code: (+ 31) 20 675 4002

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

Title of each class
Ordinary shares, par value €0.03 per share

Name of each exchange on which registered
Nasdaq Stock Market LLC
(NASDAQ Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

Edgar Filing: Tornier N.V. - Form 10-K

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☐ Yes ☐ No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

(Check one):

Large accelerated
filer ☐

Accelerated
filer ☐

Non-accelerated
filer ☒

Smaller reporting
company ☐

(Do not check if a
smaller reporting
company)

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

The aggregate market value of ordinary shares held by non-affiliates of the registrant on April 4, 2010, the last business day of the registrant's most recently completed second fiscal quarter, is not applicable as the registrant was not publicly traded as of April 4, 2010. The aggregate market value of ordinary shares held by non-affiliates of the registrant on March 7, 2011 was \$175,218,569 based on the closing sale price of the ordinary shares on the NASDAQ Global Select Market on that date. For purposes of the foregoing calculation only, the registrant has assumed that all officers and directors of the registrant are affiliates.

As of March 7, 2011 there were 39,039,994 ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

Table of Contents

**TORNIER N.V.
ANNUAL REPORT ON FORM 10-K**

Table of Contents

	Page
<u>Part I</u>	
<u>Item 1. Business.</u>	<u>5</u>
<u>Item 1A. Risk Factors.</u>	<u>24</u>
<u>Item 1B. Unresolved Staff Comments.</u>	<u>53</u>
<u>Item 2. Properties.</u>	<u>53</u>
<u>Item 3. Legal Proceedings.</u>	<u>54</u>
<u>Item 4. (Removed and Reserved).</u>	<u>55</u>
<u>Part II</u>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	<u>56</u>
<u>Item 6. Selected Financial Data.</u>	<u>57</u>
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	<u>59</u>
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk.</u>	<u>80</u>
<u>Item 8. Financial Statements and Supplementary Data.</u>	<u>82</u>
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	<u>116</u>
<u>Item 9A. Controls and Procedures.</u>	<u>116</u>
<u>Item 9B. Other Information.</u>	<u>116</u>
<u>Part III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance.</u>	<u>117</u>
<u>Item 11. Executive Compensation.</u>	<u>126</u>
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	<u>147</u>
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence.</u>	<u>150</u>
<u>Item 14. Principal Accountant Fees and Services.</u>	<u>154</u>
<u>Part IV</u>	
<u>Item 15. Exhibits, Financial Statement Schedules.</u>	<u>155</u>
<u>Signatures</u>	<u>163</u>

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains both historical and "forward-looking statements." All statements other than statements of historical fact included in this annual report 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, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained throughout this annual report, including but not limited to statements under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 forward-looking statements. Many factors mentioned in our discussion in this annual report will be important in determining future results. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Forward-looking statements (including oral representations) are only predications or statements of current plans, which we review continuously. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including, among other things, risks associated with:

a history of operating losses and negative cash flow;

not successfully developing and marketing new products and technologies and implementing our business strategy;

successful competition against our existing or potential competitors;

deriving a significant portion of our sales from operations in international markets that are subject to political, economic and social instability;

our private label manufacturers failing to provide us with sufficient supply of their products, or failing to meet appropriate quality requirements;

the loss of one of our key suppliers, and the inability to meet customer orders for our products in a timely manner or within our budget that may result;

our patents and other intellectual property rights not adequately protecting our products, and the loss of market share to our competitors that may result;

the incurrence of significant expenditures of resources to maintain relatively high levels of inventory, which can reduce our cash flows;

recent turmoil in the credit markets and the financial services industry may negatively affect our business;

the inability to raise capital when needed, which would force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.

restrictive covenants in our outstanding debt agreements that may limit our operating flexibility;

Edgar Filing: Tornier N.V. - Form 10-K

consolidation in the healthcare industry that 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 results of operations;

Table of Contents

regulatory clearances or approvals and the extensive regulatory requirements that we are subject to;

the compliance of our medical devices with the laws and regulations of the foreign countries in which they are marketed, which compliance may be costly and time-consuming; and

the use, misuse or off-label use of our products that 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.

Table of Contents

PART I

Item 1. Business.

Overview

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 80 product lines in approximately 35 countries.

We have had a tradition of innovation, intense focus on surgeon education and commitment to advancement of orthopaedic technology since our founding approximately 70 years ago in France by René Tornier. Our history includes the introduction of the porous orthopaedic hip implant, the application of the Morse taper, which is a reliable means of joining modular orthopaedic implants, and, more recently, the introduction of the reversed shoulder implant in the United States. This track record of innovation over the decades stems from our close collaboration with leading orthopaedic surgeons and thought leaders throughout the world.

We were acquired in 2006 by an investor group led by Warburg Pincus (Bermuda) Private Equity IX, L.P., or WP Bermuda, and medical device investors, including The Vertical Group, L.P., or The Vertical Group, Split Rock Partners, L.P., or Split Rock, and Douglas W. Kohrs, our Chief Executive Officer, collectively, the Investor Group. They recognized the potential to leverage our reputation for innovation and our strong extremity joint portfolio as a platform upon which they could build a global company focused on the rapidly evolving upper and lower extremity specialties. The Investor Group has contributed capital resources and a management team with a track record of success in the orthopaedic industry in an effort to expand our product offerings in extremities and accelerate our growth. Since the acquisition in 2006, we have:

created a single, extremity specialist sales channel in the United States primarily focused on our products;

enhanced and broadened our portfolio of shoulder joint implants and foot and ankle products;

entered the sports medicine and biologics markets through acquisitions and licensing agreements;

improved our hip and knee product offerings, helping us gain market share internationally; and

significantly increased investment in research and development and expanded business development activities to build a pipeline of innovative new technologies.

We believe we are differentiated by our full portfolio of upper and lower extremity products, our dedicated 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 already among the global leaders in the shoulder and ankle joint replacement markets. We more recently have expanded our technology base and product offering to include: new joint replacement products based on new 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 single, "specialists serving specialists" distribution channel 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.

Table of Contents

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 products include joint replacement and bone fixation devices for the shoulder, hand, wrist and elbow. Our lower extremity 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 mechanically repair tissue-to-tissue or tissue-to-bone injuries, in the case of sports medicine, or to support or induce remodeling and regeneration of tendons, ligaments, bone and cartilage, in the case of biologics. Our large joints and other products include hip and knee joint replacement implants and ancillary products.

This annual report contains references to among others, our trademarks Aequalis®, Affiniti , Ascend , Biofiber , CoverLoc , Futura , Insite®, InSpyre , Intrafocal , HLS Kneetec®, Latitude®, Linea , Meije Duo®, NexFix , Noetos®, Oceane , Osteocure®, Piton®, Pleos®, RFS , Salto®, Salto Talaris®, Simpliciti , Stayfuse and Tornier . All other trademarks or trade names referred to in this annual report on Form 10-K are the property of their respective owners.

Innovations in the orthopaedic industry have typically consisted of evolutions of product design in implant fixation, joint mechanics, and instruments and modifications of existing metal or plastic-based device designs rather than new products based on combinations of new designs and new materials. In contrast, the growth of our target markets has been driven by the development of products that respond to the particular mechanics of small joints and the importance of soft tissue to small joint stability and function. We are committed to the development of new designs utilizing both conventional materials and new tissue-friendly biomaterials that we expect will create new markets. We believe that we are a leader in researching and incorporating some of these new technologies across multiple product platforms.

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 market large joints in the United States nor do we currently have plans to do so. While we market our products to extremity specialists, our revenue is generated from sales to healthcare institutions and distributors. We sell through a single sales channel consisting of a network of independent commission-based sales agencies. Internationally, where the trend among surgeons toward specialization is not as advanced as in the United States, 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 independent distributors for most other international markets. In 2010, we generated revenue of \$227.4 million, 56% of which was in the United States and 44% of which was international.

Our Business Strategies

Our goal is to strengthen our leadership position serving extremity specialists. The key elements of our strategy include:

Leveraging our "specialists serving specialists" strategy: We believe our focus on and dedication to extremity specialists enables us to better understand and address the clinical needs of these surgeons. We believe that extremity specialists, who have emerged as a significant constituency in orthopaedics only in the last 10 to 15 years, have been underserved in terms of new technology and also inefficiently served by the current marketplace. We offer a comprehensive portfolio of extremity products, and also serve our customers through a sales channel that is dedicated to extremities, which we believe provides us with a significant competitive advantage, because our sales agencies and their representatives have both the knowledge and desire to comprehensively meet the needs of extremity specialists and their patients, without competing priorities.

Table of Contents

Advancing scientific and clinical education: We believe our specialty focus, commitment to product innovation and culture of scientific advancement attract both thought leaders and up-and-coming surgeon specialists who share these values. We actively involve these specialists in the development of world-class training and education programs and encourage ongoing scientific study of our products. Specific initiatives include the Tornier Master's Courses in shoulder and ankle joint replacement, The Fellows and Chief Residents Courses, and a number of clinical concepts courses. We also maintain a registry that many of our customers utilize to study and report on the outcomes of procedures in which our extremity products have been used. We believe our commitment to science and education also enables us to reach surgeons early in their careers and provide them access to a level of training in extremities that we believe is not easily accessible through traditional orthopaedic training.

Introducing new products and technologies to address more of our extremity specialists' clinical needs: Our goal is to continue to introduce new technologies for extremity joints that improve patient outcomes and thereby continue to expand our market opportunity and share. Our efforts have been focused on joint replacement, as well as sports medicine and biologics, given the importance of these product categories to extremity surgeons. Since our acquisition by the Investor Group, we have significantly increased our investment in research and development to accelerate the pace of new product introduction. We have also been active in gaining access to new technologies through external partnerships, licensing agreements and acquisitions. We believe that our reputation for effective collaboration with industry thought leaders as well as our track record of effective new product development and introductions will allow us to continue to gain access to new ideas and technologies early in their development.

Expanding our international business: We face a wide range of market dynamics that require our distribution channels to address both our local market positions and local market requirements. For example, in France, which is a more developed extremities market and where we have a diversified extremities, hip and knee business, we have two direct sales organizations. One is focused on products for upper extremities, and the other focused on hip and knee replacements and products for lower extremities. In other European markets, we utilize a combination of direct and distributor strategies that have evolved to support our expanding extremity business and also to support our knee and hip market positions. In large international markets where the extremity market segment is relatively underdeveloped, such as Japan and China, the same sales channel sells our hip and knee product portfolios and extremity joint products, which provides these sales channels sufficient product breadth and economic scale. We plan on expanding our international business by continuing to adapt our distribution channels to the unique characteristics of individual markets.

Achieving and improving our profitability through operating leverage: With the additional capital resources brought by the Investor Group, we have made significant investments over the last several years in our research and development, sales and marketing, and manufacturing operations to build what we believe is a world-class organization capable of driving sustainable global growth. For example, we grew our research and development organization from approximately 20 employees as of December 31, 2006 to 83 employees as of January 2, 2011. We created a new global sales and marketing leadership team by integrating key personnel from acquired organizations and recruiting additional experienced medical device sales and marketing professionals. We also expanded our manufacturing capacity with two new plants in Ireland and France. With these organizational and infrastructure investments in place, we believe we have the infrastructure to support our growth for the foreseeable future. As a result, we believe we can increase revenue and ultimately achieve and improve profitability.

Table of Contents

Our Surgeon Customers

We estimate that there are over 80,000 orthopaedic and over 9,000 podiatric surgeons worldwide who specialize in surgical treatment of the musculoskeletal system, including bones, joints and soft tissues such as tendons and ligaments. In the United States and certain other developed markets, there has been a trend over the past two decades for these surgeons to specialize in certain parts of the anatomy or certain types of procedures. We believe that the trend toward specialization has been supported by the expansion of specialist professional societies and an increase in the number of fellowship programs. We focus on the following orthopaedic specialist groups:

Upper Extremity Specialists: Upper extremity specialists perform joint replacement and trauma and soft tissue repair procedures for the shoulder, elbow, wrist and hand. We believe the evolution of this specialty has been driven by the unique requirements of these joints due to the relative importance of soft tissue to joint function and the increased complexity and breadth of technology available for use in these procedures. For this reason, in addition to joint replacement and trauma products, upper extremity specialists utilize a broad range of sports and orthobiologic products. We believe upper extremity specialists now perform the majority of shoulder joint replacements that were previously performed by reconstructive and general orthopaedic surgeons.

Lower Extremity Specialists: Lower extremity specialists perform a wide range of joint replacement, trauma, reconstruction and soft tissue repair procedures for the foot and ankle. This specialist group principally consists of orthopaedic surgeons who have received fellowship or other specialized training. Additionally, Doctors of Podiatric Medicine with special surgical training may perform certain foot and ankle surgical procedures in the United States, Canada and United Kingdom.

Sports Medicine Specialists: Sports medicine specialists are surgeons who use minimally invasive surgical techniques, including arthroscopy, for the repair of soft tissues. Arthroscopy is a minimally invasive surgical technique in which a surgeon creates several small incisions at the surgery site; inserts a fiber optic scope with a miniature video camera as well as surgical instruments through the incisions to visualize, access and conduct the procedure; and uses a video monitor to view the surgery itself. The sports medicine specialty is not just limited to treatment of athletes, but rather to all patients with orthopaedic soft tissue injuries or disease. The most common sports medicine procedures are ligament repairs in the knee and rotator cuff tendon repairs in the shoulder.

Reconstructive and General Orthopaedic Surgeons: Reconstructive and general orthopaedic surgeons are important customers for us in selected European countries and other international markets. In these markets, orthopaedic surgeons may treat multiple areas of bone and joint disease and trauma, and commonly perform procedures involving extremity joints as well as hip and knee joint replacement. For these target customers, we are able to provide not only our broad product category for extremity joint procedures, but also our hip and knee joint replacement products.

Our Target Markets

We compete on a worldwide basis providing upper and lower extremity specialist surgeons a wide range of products from several major segments of the orthopaedic market, including extremity joints, sports medicine, biologics and trauma. In addition, we compete in the hip and knee segments of certain international markets where we have a strong legacy presence such as in France, where participation in the local hip and knee market is important to our distributor partners, and in China, where the market for our extremity focused products is still small.

We believe our addressable portion of the market will grow at a faster rate than the overall orthopaedic market due to the introduction of new technologies with improved clinical outcomes, a growing number of extremity specialists, the aging of the general population and the desire for people

Table of Contents

to remain physically active as they grow older. Overviews of the major orthopaedic markets in which we compete, as well as our targeted participation in those markets, are as follows:

Extremity Joints: The extremity joint market includes implantable devices used for the replacement of shoulder, elbow, hand, and foot and ankle joints. We believe this market has been under-served and underdeveloped by major orthopaedic companies, which have generally focused on the much larger hip, knee and spine markets. As a result, the growth of the extremity joint market is still benefiting from market-expanding design and materials technologies and from growth in the number of upper and lower extremity specialists. We believe that we are a leader in both the shoulder and ankle joint replacement portions of this market based upon revenue.

Sports Medicine: Sports medicine refers to the repair of soft tissue injuries that often occur when people are engaged in physical activity, but that also result from age-related wear and tear. We believe market growth has been driven by both new technology and the continued acceptance of minimally invasive surgical techniques. The most common sports medicine procedures are anterior cruciate ligament repairs in the knee and rotator cuff repairs in the shoulder. The primary sports medicine products include capital equipment and related disposables as well as bone anchors, which are implantable devices used to attach soft tissue to bone, sutures, or thread for soft tissue, and handheld instruments. We estimate that our products currently address only a portion of the sports medicine market, primarily bone anchors and other products utilized for rotator cuff repairs. The total sports medicine market also includes capital or powered equipment and related disposables, but we do not have any product offerings in these areas.

Biologics: Biologics refer to products, both biologic and synthetic, that are utilized to stimulate hard and soft tissue healing following surgery for a wide range of orthopaedic injuries or disorders. We believe market growth is being driven by the application of an expanding biotechnology knowledge base to the development of products that can improve clinical outcomes by inducing tissue healing and regeneration. The primary product categories in the total biologics market are bone grafting materials, cell therapy systems, including growth factors, and tendon and ligament grafts. We currently only offer tendon and ligament graft products for extremities.

Trauma: The trauma market includes devices that are used to treat fractures, joint dislocations, severe arthritis and deformities that result from either acute injuries or chronic wear and tear. The major products in the trauma market include metal plates, screws, pins, wires and external fixation devices used to hold fractured bone fragments together until they heal properly. These devices are also utilized in the treatment of a wide range of non-traumatic surgical procedures, especially in the foot and ankle. As the market has transitioned from external casting performed in the emergency room, to internal fixation performed on a scheduled basis in the operating room, our extremity specialist customers have expanded their role in treating trauma injuries. Our products currently address only a portion of the trauma market, consisting primarily of plating systems, screws and pins for the repair of extremity joint injuries and disorders.

Knee Joints: Knee joint replacements are performed for patients who have developed an arthritic condition that compromises the joints' articulating surfaces (articulating surfaces are bone segments connected by a joint). The knee joint replacement system has multiple components including a femoral component, a tibial component and a patella component (knee cap). We currently provide a broad line of knee joint replacement products in selected international geographies. We do not currently address the knee joint market in the United States.

Hip Joints: Hip joint replacements are performed for patients who have suffered a femoral fracture or suffer from severe arthritis or other conditions that have led to the degradation of the articular cartilage or bone structure residing between the femoral head and the acetabulum (hip socket). The hip joint replacement system generally includes both femoral and acetabular components.

Table of Contents

We currently provide a broad line of hip joint replacement products in selected international geographies. We do not currently address the hip joint market in the United States.

Our Product Portfolio

We offer a broad product line designed to meet the needs of our extremity specialists and their patients. Although the industry traditionally organizes the orthopaedic market based on the mechanical features of the products, we organize our product categories in a way that aligns with the types of surgeons who use them. Therefore, we distinguish upper extremity joints and trauma from lower extremity joints and trauma, as opposed to viewing joint implants and trauma products as distinct product categories. Along these lines, our product offering is as follows:

Product category	Target addressable geography
Upper extremity joints and trauma	United States and International
Lower extremity joints and trauma	United States and International
Sports medicine and biologics	United States and International
Large joints and other	Selected International Markets

See Fiscal Year Comparisons contained in the Management's Discussion and Analysis of Financial Condition and Results of Operation section of this filing for three-year revenue history by product category.

Upper Extremity Joints and Trauma

The upper extremity joints and trauma product category includes joint implants and bone fixation devices for the shoulder, hand, wrist and elbow. Our global revenue from this category for the year ended January 2, 2011 was \$139.2 million, or 61% of revenue, which represents growth of 11% over the prior fiscal year.

Shoulder Joint Replacement and Trauma Implants We expect the shoulder to continue to be the largest and most important product category for us for the foreseeable future. Our shoulder joint implants are used to treat painful shoulder conditions due to arthritis, irreparable rotator cuff tendon tears, bone disease, fractured humeral heads or failed previous shoulder replacement surgery. Our products are designed for the following:

Our total joint replacement products have two components – a humeral implant consisting of a metal stem attached to a metal ball, and a plastic implant for the glenoid (shoulder socket). Together, these two components mimic the function of a natural shoulder joint.

Our hemi joint replacement products replace only the humeral head and allow it to articulate against the native glenoid.

Our reversed implants are used in arthritic patients lacking rotator cuff function. The components are different from a traditional "total" shoulder in that the humeral implant has the plastic socket and the glenoid has the metal ball. This design has the biomechanical impact of shifting the pivot point of the joint away from the body centerline and giving the deltoid muscles a mechanical advantage to enable the patient to elevate the arm.

Our resurfacing implants are designed to minimize bone resection to preserve bone, which may benefit more active or younger patients with shoulder arthritis.

Trauma devices, such as plates, screws and nails, are non-articulating implants used to help stabilize fractures of the humerus.

Table of Contents

Hand, Wrist and Elbow Joint Replacement and Trauma Implants We offer joint replacement products that are used to treat arthritis in the hand, wrist and elbow. In addition, we offer trauma products including plates, screws and pins, to treat fractures of the hand, wrist and elbow. One of our distinctive product offerings for these smaller, non-load bearing joints are implants made from a biocompatible material called pyrocarbon, which has low joint surface friction and a high resistance to wear. We offer a wide range of pyrocarbon implants internationally and have begun to introduce some of these products into the United States.

Lower Extremity Joints and Trauma

Our global revenue from lower extremity joints and trauma for the year ended January 2, 2011 was \$23.6 million, 10% of revenue, which represents growth of 16% over the prior fiscal year.

Ankle Joint Implants Ankle arthritis is a painful condition that can be treated by fusing the ankle joint with plates or screws or by replacing the joint with an articulating multi-component implant. These joint implants may be mobile bearing, in which the plastic component is free to slide relative to the metal bearing surfaces, or fixed bearing, in which this component is constrained. Precision bearing implants are highly anatomic fixed bearing implants.

Other Foot and Ankle Joint and Trauma Implants Our products include joint replacement implants to treat arthritis of the toes and other small bone joints, trauma and bone fusion implants for the foot and ankle, and other implants to address certain other deformities of the foot.

Sports Medicine and Biologics

Our revenue from sports medicine and biologics for the year ended January 2, 2011 was \$13.2 million, or 6% of overall revenue, which represents growth of 100% in that segment over the prior fiscal year. Nearly all of our products in this product category were launched during the first half of 2009 and only in the United States. We have introduced some of these products internationally in 2010.

Sports Medicine The sports medicine product category includes products used across several anatomic sites to mechanically repair tissue-to-tissue or tissue-to-bone injuries. Because of its close relationship to shoulder joint replacement, the sports medicine market is of critical strategic importance to us. Rotator cuff repair is the largest sub-segment in the sports medicine market. Other procedures relevant to extremities include shoulder instability treatment, Achilles tendon repair and soft tissue reconstruction of the foot and ankle and several other soft tissue repair procedures.

Biologics The field of biologics employs tissue engineering and regenerative medicine technologies focused on remodeling and regeneration of tendons, ligaments, bone and cartilage. Biologically or synthetically derived soft tissue grafts and scaffolds are used to treat soft tissue injuries and are complementary to many sports medicine applications, including rotator cuff tendon repair and Achilles tendon repair. Hard tissue biologics products are used in many bone fusion or trauma cases where healing potential may be compromised and additional biologic factors are desired to enhance healing, where the surgeon needs additional bone stock and does not want to harvest a bone graft from another surgical site or in cases where the surgeon wishes to use materials that are naturally incorporated by the body over time in contrast to traditional metallic-based products that may require later removal.

We have a robust pipeline of biologics products under development and are actively pursuing new product additions. We have in-licensed biologic materials such as Biofiber, an advanced high-strength resorbable polymer fiber produced using recombinant DNA technology as well as our F2A peptide, a synthetic version of the natural human FGF-2 growth factor.

Table of Contents

Large Joints and Other

The large joints and other product category includes hip and knee joint replacement implants and ancillary products. Hip and knee joint replacements are used to treat patients with painful arthritis in these larger joints. Our global revenue from large joints and other products for the year ended January 2, 2011 was \$51.4 million, or 23% of overall revenue, which represents growth of 5% over the prior fiscal year.

We generated nearly all of our revenue from this category outside of the United States. We have continued to innovate in this area so that we can maintain or grow market share in several international markets where the extremity markets have not yet reached a size to permit the type of channel focus that we have in the United States or where extremities specialization is not as prevalent as in the United States. We currently have no plans to actively market our large joint implants in the United States.

Our Technologies

The orthopaedic industry has produced many innovations in product design over the years. These innovations have typically consisted of evolutions of product design in implant fixation, joint mechanics, and instruments and modifications of existing metal or plastic-based device designs rather than new products based on combinations of new designs and new materials. In contrast, the growth of our target markets has been driven by the development of products that respond to the particular mechanics of small joints and the importance of soft tissue to small joint stability and function. We are committed to the development of new designs utilizing both conventional materials and new tissue-friendly biomaterials that we expect will create new product categories. We believe that we are a leader in researching and incorporating some of these new technologies across multiple product platforms. A few selected examples are listed below:

Advanced Design Technologies

Bone sparing implants: Several of our newer implants, such as our Ascend shoulder, Simpliciti shoulder and InSpyre shoulder, as well as our current implants, such as our Salto Talaris ankle implant, follow a philosophy of bone sparing site preparation to minimize the amount of native tissue that must be removed for the implant. We believe this philosophy results in a more anatomic implant that is less traumatic to the patient. By preserving native tissue, we believe surgeons retain more options compared to traditional implants should a revision procedure be required in the future.

Adjustable locking plates: We have incorporated CoverLoc technology into some of our plating systems, including wrist and ankle plates. CoverLoc technology is based upon high precision machining that places screw holes through metal plates at anatomic angles. Each hole is angled to achieve optimal screw or peg placement aimed at reducing the risk of screw loosening. Furthermore, the technology provides the surgeon the ability to pull bone fragments to the plate and then lock the screws in the desired angle with the cover plate, while providing protection for the surrounding soft tissues from the screw heads.

Knotless suture locking: Cinch technology is a patented mechanism that is the basis for our knotless suture anchor platform. The Piton suture anchor is the first product to incorporate Cinch technology. Cinch technology eliminates the need for knots while allowing surgeons to independently and sequentially tension each suture, even after inserters are removed. We believe this innovative design makes it easier for surgeons to perform arthroscopic surgery, eliminates knot slippage, and enables a uniform soft tissue repair across the repaired surface.

Table of Contents

Advanced Materials

Pyrocarbon: This material is gaining acceptance for use in orthopaedics due to its biocompatibility, low joint surface friction and high resistance to wear. Pyrocarbon also has a stiffness similar to bone, making it an ideal material for orthopaedic implants. We offer several joint replacement or joint spacer devices made from pyrocarbon in the hand, wrist and elbow, and have recently announced what we believe to be the first human implant of a pyrocarbon shoulder implant.

Resorbable polymers: Some of our products utilize resorbable polymers, the benefit of which is that once a soft tissue injury has healed and the implant is no longer necessary, there is no longer a foreign substance residing in the body. Our Biofiber material is a high-strength resorbable polymer that can be processed in many physical configurations including fiber, mesh and film. These materials are biocompatible and non-inflammatory. They degrade by cell-friendly processes into metabolites that already exist in humans, unlike other acidic bioresorbable materials. We also offer high strength next-generation resorbable materials in our Resorbable Fixation System product line of trauma pins and screws. These products benefit from a combination of materials having a long history of surgical use and our supplier's ability to produce a high-strength, reliable, biodegradable implant.

Biologic Technologies

Biologic tissue grafts: Our Conexa reconstructive tissue matrix product line was introduced through a partnership with LifeCell, a division of KCI. The Conexa material provides a complex three-dimensional biologic architecture to support cellular repopulation and vascular channels that allow for rapid capillary in-growth. Surgeons use this product in procedures to support regeneration of soft tissue, such as rotator cuff and Achilles tendon repairs.

Synthetic Growth Factors: F2A is an engineered peptide that is a synthetic version of the natural human FGF-2 growth factor. FGF-2 and other naturally occurring growth factors may play key roles in the body's healing and repair processes. Synthetic growth factors may address many of the manufacturing, handling and shelf life challenges that have limited the clinical role of natural growth factors. We have recently conducted pre-clinical testing of a scaffold incorporating F2A that demonstrates tissue regeneration in both small and large animal models. F2A has not yet been approved by the FDA.

Distribution

We have developed our distribution channels to serve the needs of our customers, primarily extremity specialist surgeons in the United States and a mix of extremity specialist and general orthopaedic surgeons in international markets. In the United States, we have a broad offering of joint replacement and repair, sports and biologic products targeting extremity specialists through a single distribution channel. Internationally, we utilize several distribution approaches depending on individual market requirements. We utilize direct sales organizations in several mature European markets and independent sales agencies for most other international markets. In France, we have two direct sales forces, one handling our upper extremity focused products and one handling our lower extremity portfolio. In emerging international markets such as China and Japan, where extremity markets are still undeveloped, we utilize independent sales agencies that carry both our extremity-focused and our hip and knee portfolios.

United States

In the United States, we sell upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics products. We do not actively market hip or knee replacement joints in

Table of Contents

the United States, although we have FDA clearance for selected large joint products. We sell our products through a single sales channel. Our U.S. sales force consists of a network of approximately 24 independent commission-based sales agencies, which in aggregate utilized over 300 sales representatives as of January 2, 2011, many of whom exclusively sell our products. We believe a significant portion of these sales agencies' commission revenue is generated by sales of our products. Our success depends largely upon our ability to motivate these sales agencies and their representatives to sell our products. Additionally, we depend on their sales and service expertise and relationships with the surgeons in the marketplace. Our independent sales agencies are not obligated to renew 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. A failure to maintain our existing relationships with our independent sales agencies and their representatives could have an adverse effect on our operations. We do not control our independent sales agencies and they may not be successful in implementing our marketing plans. We employ four area business directors to support these independent sales agencies and have dedicated marketing support, to help drive adoption of our newly introduced extremities, sports and biologics products. During the course of the year, we host numerous opportunities for product training throughout the United States.

International

We sell our full product portfolio, including upper and lower extremities, sports medicine and biologics and large joints, in select international markets. We believe our full range of hip and knee products enable us to more effectively and efficiently service these markets where procedure or anatomic specialization is not as prevalent as in the United States and where extremities, sports medicine and biologics markets have not yet reached a size to permit the degree of channel focus we have in the United States. Our international distribution system consists of nine direct sales offices and approximately 32 distributors that sell our products in approximately 35 countries. Our largest international market is France, where we have a direct sales force of 26 direct sales representatives. We also have direct sales offices and corporate subsidiaries in Germany, Italy, Spain, Switzerland, the Netherlands, the United Kingdom, Denmark and Australia that employ direct sales employees. Additional European countries, as well as countries in Latin America and Asia, are served by distributors who purchase products directly from us for resale to their local customers, with product ownership generally passing to the distributor upon shipment. As part of our strategy to grow internationally, we have selectively converted from distributors to direct sales representation in certain countries, as we did in the United Kingdom and Denmark in 2009. We intend to focus on expanding our presence in underserved countries, such as China, where we signed an agreement in 2009 with Weigao for the exclusive distribution of our shoulder, hip and knee products for a four-year term. Purchase quotas and prices are set at the end of each year and the agreement may be terminated prior to its expiration in 2014 upon breach by either party, including Weigao's failure to meet the purchase quota.

Our total revenue in France was \$47.3 million in 2010, \$46.3 million in 2009 and \$43.2 million in 2008. Our total revenue in the Netherlands was \$4.1 million in 2010, \$3.6 million in 2009 and \$3.4 million in 2008.

Research and Development

We are committed to a strong research and development program and have significantly increased our investment in this area since the acquisition by the Investor Group in 2006. Our research and development expenses were \$17.9 million, \$18.1 million and \$20.6 million in 2010, 2009 and 2008, respectively. As of January 2, 2011, we had a research and development staff of 83 people, or 10% of total employees, principally located in Montbonnot, France and Warsaw, Indiana, with additional staff in Grenoble, France, San Diego, California and Boston, Massachusetts.

Table of Contents

We have dedicated internal product development teams focused on continuous innovation and introduction of new products for extremity joint replacements, extremity joint trauma, soft tissue repair and large joint replacement. We also have an active business development team that seeks to in-license development-stage products, which our internal team assists in bringing to market. In collaboration with our internal teams, we work closely with external research and development consultants and a global network of leading surgeon inventors to ensure we have broad access to best-in-class ideas and technology to drive our product development pipeline.

Manufacturing and Supply

We manufacture substantially all of our products at five sites including Montbonnot, Saint-Ismier and Grenoble, France, and Dunmanway and Macroom, Ireland. Our operations in France have a long history and deep experience with orthopaedic manufacturing and innovation and we have invested in facilities upgrades to both expand capabilities and establish incremental lean cellular manufacturing practices there as well. Our Ireland locations have been practicing lean cellular manufacturing concepts for many years with a philosophy focused on continuous operational improvement and optimization. We continually evaluate the potential to in-source products currently purchased from outside vendors to on-site production. We are continuously working on product and process improvement projects to optimize our manufacturing processes and product costs to improve our profitability and cash flow. We believe that our manufacturing facilities and relationships will support our potential capacity needs for the foreseeable future.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select components used in manufacturing our products from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, cost-effectiveness or constraints resulting from regulatory requirements. 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 pyrocarbon on a purchase order basis, Heymark Metals Ltd., which supplies CoCr used in certain of our hip, shoulder and elbow products on a purchase order basis, and CeramTec Group, which supplies ceramic for ceramic heads for hips on a purchase order basis.

We believe we are the only vertically integrated manufacturer of pyrocarbon orthopaedic products with production equipment to enable production of larger-sized implants. While we rely on an external supplier to supply us with surgical grade substrate material, we control the remaining pyrocarbon manufacturing process, which we believe gives us a competitive advantage in design for manufacturing and prototyping of this innovative material.

We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty in locating and obtaining the materials necessary to fulfill our production requirements.

Some of our products are provided by suppliers under private-label distribution agreements. Under these agreements, the supplier generally retains the intellectual property and exclusive manufacturing rights. The supplier private labels the products under the Tornier brand for sale in certain fields of use and geographic territories. These agreements may be subject to minimum purchase or sales obligations.

Our private-label distribution agreements expire between 2011 and 2015 and are renewable under certain conditions or by mutual agreement. These agreements are terminable by either party upon notice and such agreements 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 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

Table of Contents

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.

Our private-label distribution agreements do not, individually or in the aggregate, represent a material portion of our business and we are not substantially dependent on them.

Competition

The market for orthopaedic devices is highly competitive and subject to rapid and profound technological change. Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. We believe that the principal competitive factors in our markets include product features and design, reputation and service. One of the key factors to our future success will be our ability to continue to introduce new products and improve existing products and technologies. In addition, we are committed to following the AdvaMed and Eucomed guidelines and codes of ethics in our interactions with customers and other healthcare professionals globally.

We face competition from large diversified orthopaedic manufacturers, such as DePuy, Zimmer and Stryker, and established mid-sized orthopaedic manufacturers, such as Arthrex, Wright Medical and ArthroCare. Many of the companies developing or marketing competitive orthopaedic products are publicly traded or are divisions of publicly traded companies and may enjoy several competitive advantages, including:

greater financial and human resources for product development and sales and marketing;

significantly 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 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 clearance 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 our competitors in recruiting and retaining qualified scientific and management 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, our business may be harmed.

Intellectual Property

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

Edgar Filing: Tornier N.V. - Form 10-K

Although we believe our patents are valuable, our knowledge and experience, our creative product development and marketing staff, and our trade secret information with respect to manufacturing

Table of Contents

processes, materials and product design, have been equally important in maintaining our proprietary product lines. As a condition of employment, we generally require employees to execute a confidentiality agreement relating to proprietary information and assigning patent rights to us. We cannot be assured that our patents will provide competitive advantages for our products, or that our competitors will not challenge or circumvent these rights. In addition, we cannot be assured that the United States Patent and Trademark Office, or USPTO, or foreign patent offices will issue any of our pending patent applications. The USPTO and foreign patent offices may also deny or require significant narrowing of claims in our pending patent applications and patents issuing from the pending patent applications. Any patents issuing from our pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO or foreign patent offices, including interference or opposition proceedings. These proceedings could result in adverse decisions as to the priority of our inventions. Additionally, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as the laws in the United States, or at all.

While we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by third parties, we cannot be assured that we do not infringe any patents or other proprietary rights held by third parties. If our products were found to infringe any proprietary right of a third party, we could be required to pay significant damages or license fees to the third party or cease production, marketing and distribution of those products. Litigation may also be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own.

We also rely on trade secrets and other unpatented proprietary technology. We cannot be assured that we can meaningfully protect our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants. We cannot be assured, however, that the agreements will not be breached, that we will have adequate remedies for any breach or that our competitors will not discover or independently develop our trade secrets.

Corporate History

We were founded in the 1940s by René Tornier in Saint-Ismier, France and are one of the early pioneers of the orthopaedic implant market. We originally manufactured dental surgical products, and diversified into screws and plates for orthopaedic surgery in the 1950s, and entered the joint replacement market with a hip implant in the 1960s. Alain Tornier, René Tornier's son, began to work for us in 1970 and assumed a leadership role in 1976 when René Tornier died. Alain Tornier modernized our manufacturing; organized and expanded commercial operations with a direct sales force in France; introduced a knee implant product line; and established our first international subsidiary in Spain. During the 1990s and early 2000s, Alain Tornier continued to improve upon our growth by introducing new products and expanding into new international markets. In 2006, Alain Tornier sold a majority stake in us to the Investor Group, but retained a minority equity position and became a non-executive director.

Table of Contents

Since the acquisition by the Investor Group, we have significantly increased our investment in research and development, from \$3.0 million in 2006 to \$17.9 million in 2010. In addition, we have expanded our product portfolio and ability to serve our target customers through a series of strategic acquisitions, licensing and distribution agreements. Each of these transactions was specifically targeted for its potential to either improve our ability to compete in an existing market or expand our addressable market by broadening our product portfolio into a related area. The entry into the sports medicine market in particular expanded our addressable market to include the core products used by our shoulder surgeon customers, who typically perform both shoulder joint replacement and shoulder sports medicine procedures. In addition, we have been active in licensing new material technologies with longer-term potential to differentiate our product offering. Finally, we expanded geographically in selected international markets.

Regulatory Matters

FDA Regulation

Both before and after approval or clearance our products and product candidates are subject to extensive regulation. In the United States, we are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act, as well as other regulatory bodies. These regulations govern, among other things, the following activities in which we and our contract manufacturers, contract testing laboratories and suppliers are involved:

product development;

product testing;

product manufacturing;

product labeling;

product safety;

product storage;

product market clearance or approval;

product advertising and promotion;

product import and export; and

product sales and distribution.

Failure to comply with the Federal Food, Drug, and Cosmetic Act could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension on withdrawal of product approval, injunctions or criminal prosecution.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on risk and the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy. These classifications generally require the following:

Edgar Filing: Tornier N.V. - Form 10-K

Class I: general controls, such as labeling and adherence to quality system regulations;

Class II: general controls, premarket notification (510(k)) and special controls such as performance standards, patient registries and postmarket surveillance; and

Class III: general controls and approval of a PMA.

Table of Contents

Most of our new products fall into FDA classifications that require the submission of a Premarket Notification (510(k)) to the FDA. In the 510(k) process, the FDA reviews a premarket notification and determines whether a proposed device is "substantially equivalent" to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of PMA applications, referred to as a predicate device. In making this determination, the FDA compares the proposed device to the predicate device. If the two devices are comparable in intended use and safety and effectiveness, the device may be cleared for marketing. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding the proposed device to be substantially equivalent to the predicate. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then the company must submit and the FDA must approve a PMA before marketing can begin.

Other devices we may develop and market may be classified as Class III for which the FDA has implemented stringent clinical investigation and PMA requirements. The PMA process would require us to provide clinical and laboratory data that establishes that the new medical device is safe and effective. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The PMA can include post-approval conditions including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process.

All of our devices marketed in the United States have been listed, cleared or approved by the FDA. Some low-risk medical devices (including most instruments) do not require FDA review and approval or clearance prior to commercial distribution, but are subject to FDA regulations and must be listed with the FDA. The FDA has the authority to: halt the distribution of certain medical devices; detain or seize adulterated or misbranded medical devices; or order the repair, replacement of or refund the costs of such devices. There are also requirements of state, local and foreign governments that we must comply with in the manufacture and marketing of our products. For example, some jurisdictions require compliance with the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals or its equivalent. Laws and regulations and the interpretation of those laws and regulations may change in the future. We cannot foresee what effect, if any, such changes may have on us.

Clinical Trials

One or more clinical trials are almost always required to support a PMA application and are sometimes required to support a 510(k) submission. Clinical trials of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could

Table of Contents

pose a significant risk to patients, the sponsor company must submit an application for an investigational device exemption, or IDE, to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical trials of investigational devices may not begin until an institutional review board, or IRB, has approved the study.

During the trial, the sponsor must comply with the FDA's IDE requirements including, for example, for investigator selection, trial monitoring, adverse event reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and trial protocol, control the disposition of investigational devices and comply with reporting and recordkeeping requirements. We, the FDA and the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more trials supporting the application.

Post-market Regulation

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

the QSR regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over and document manufacturing of their products;

labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

the Medical Device Reporting regulation, which requires reporting to the FDA certain adverse experiences associated with use of the product.

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as do our suppliers, contract manufacturers and contract testing laboratories.

International Regulation

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

design, development, manufacturing and testing;

product standards;

product safety;

marketing, sales and distribution;

packaging and storage requirements;

labeling requirements;

Edgar Filing: Tornier N.V. - Form 10-K

content and language of instructions for use;

clinical trials;

record keeping procedures;

advertising and promotion;

recalls and field corrective actions;

Table of Contents

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

import and export restrictions; and

tariff regulations, duties and tax requirements.

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

In many of the foreign countries in which we market our products, we are subject to local regulations affecting, among other things, design and product standards, packaging requirements and labeling requirements. Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA.

In 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.

U.S. Anti-kickback and False Claims Laws

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

In particular, the federal Anti-Kickback Law prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare 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

Table of Contents

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 claim statutes. The lack of uniform interpretation of the Anti-Kickback Law makes compliance with the law difficult. The penalties for violating the Anti-Kickback Law can be severe. These sanctions include criminal penalties and civil sanctions, including fines, imprisonment and possible exclusion from participation in federal healthcare programs.

Recognizing that the Anti-Kickback Law is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services issued regulations in July of 1991, which the Department has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback law. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Law, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback law will be pursued. Even though we continuously strive to comply with the requirements of the Anti-Kickback Law, liability under the Anti-Kickback Law may still arise because of the intentions or actions of the parties with whom we do business, including our independent distributors. While we are not aware of any such intentions or actions, we have only limited knowledge regarding the intentions or actions underlying those arrangements. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities.

Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payors for reimbursement, claims that are false or fraudulent, or that are for items or services that were not provided as claimed. Although our business is structured to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by federal or state enforcement officials under these laws. This type of challenge could have a material adverse effect on our business, financial condition and results of operations.

Third-Party Coverage and Reimbursement

We anticipate that sales volumes and prices of our products will depend in large part on the availability of coverage and reimbursement from third-party payors. Third-party payors include governmental programs such as Medicare and Medicaid, private insurance plans and workers' compensation plans. These third-party payors may deny coverage or reimbursement for a product or therapy if they determine that the product or therapy was not medically appropriate or necessary. The third-party payors also may place limitations on the types of physicians that can perform specific types of procedures. Also, third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution, we may find limited demand for the device until reimbursement approval has been obtained from governmental and private third-party payors.

The Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program, sets coverage and reimbursement policies for the Medicare program in the United States. CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make

Table of Contents

coverage and payment decisions. Medicaid programs are funded by both federal and state governments, may vary from state to state and from year to year and will likely play an even larger role in healthcare funding pursuant to the PPACA.

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

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

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions prior to major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering healthcare. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

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

Employees

As of January 2, 2011, we had approximately 792 employees, including 331 in manufacturing and operations, 83 in research and development and the remaining in sales, marketing and related administrative support. Of our 792 worldwide employees, 178 employees were located in the United States and 614 employees were located outside of the United States, primarily throughout Europe.

Table of Contents

Item 1A. Risk Factors.

The following information contains specific risks that could potentially impact our business, financial condition or operating results. We may be subject to additional risks that are not currently known to us or those which we deem immaterial that may also impact our business operations.

Risks Related to Our Business and Our Industry

We have a history of operating losses and negative cash flow.

We have experienced operating losses since our acquisition by the Investor Group in July 2006 and at January 2, 2011, we had an accumulated deficit of \$183.5 million. Our ability to achieve cash flow positive operations will be influenced by many factors, including the extent and duration of our future operating losses, the level and timing of future sales and expenditures, market acceptance of new products, the results and scope of ongoing research and development projects, competing technologies and market and regulatory developments. Additionally, we expect general and administrative expenses to increase due to the additional operational and reporting costs associated with being a public company. 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 results of operations will 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 clearance or approval 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 could also 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 are 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 sales 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.

Table of Contents

We rely on our independent sales agencies and their representatives to market and sell our products.

In the United States, we sell our products through a single sales channel primarily focused on our products and consisting of approximately 24 independent commission-based sales agencies, which in the aggregate utilized over 300 sales representatives as of January 2, 2011. Our sales agencies do not sell our products exclusively and may offer similar products from other orthopaedic companies. In fiscal 2010, no individual sales agency accounted for more than 3% of our global revenue. Our success depends largely upon our ability to motivate these sales agencies to sell our products. Additionally, we depend on their sales and service expertise and relationships with the surgeons in the marketplace. Our independent sales agencies may terminate their contracts with us at the end of each yearly term, 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 sales agencies terminated, we could enter into agreements with existing sales agencies to take on the related sales, contract with new sales agencies or a combination of these options. A failure to maintain our existing relationships with our independent sales agencies and their representatives could have an adverse effect on our operations. We do not control our independent sales agencies and they may not be successful in implementing our marketing plans.

We may be unable to compete successfully against our existing or potential competitors, in which case our sales 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., or DePuy, a Johnson & Johnson subsidiary, Zimmer Corporation, or Zimmer, and Stryker Corporation, or Stryker, and established mid-sized orthopaedic manufacturers, such as Arthrex, Inc., or Arthrex, Wright Medical Group, Inc., or Wright Medical, and ArthroCare Corporation, or ArthroCare. Many of the companies developing or marketing competitive orthopaedic products are publicly traded or are divisions of publicly traded companies and may 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 we can, obtain regulatory clearance or approvals for competing products more rapidly than we can 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 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.

Table of Contents

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

We derive a significant portion of our sales from operations in international markets. Our international distribution system consists of nine direct sales offices and approximately 32 distribution partners, who sell in approximately 35 countries. Most of these countries are, to some degree, subject to political, economic and social instability. For each of the years ended January 2, 2011 and December 27, 2009, approximately 44% of our revenue was derived from our international operations. 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 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;

changes in tariffs and other trade restrictions;

work stoppages or strikes in the healthcare industry;

difficulties in enforcing and defending intellectual property rights; and

exposure to different legal and political standards.

Not only are we subject to the laws of other jurisdictions, we are also 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

Edgar Filing: Tornier N.V. - Form 10-K

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 are also subject to requirements including registration of establishment, listing of devices, manufacturing in

Table of Contents

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 sales 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 sales may negatively affect our profitability. We generate our international sales 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.

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

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. The projected demand for our products could materially differ from actual 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.

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 sales. 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 2011 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

Table of Contents

breach of the terms and 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 U.S. Food and Drug Administration, or 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.

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 results of operations.

Our U.S. operations, including those of our 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 are also 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 operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, such as Algeria, China and Oman, based on measurements such as Transparency International's Corruption Perception Index 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 have also 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 Securities and Exchange Commission, or 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

Table of Contents

by U.S. or foreign authorities also could have an adverse impact on our business, financial condition and results of operations.

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.

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

A substantial portion of our foreign revenue is generated in Europe and other foreign countries in Latin America and Asia where the amounts are denominated in currencies other than the U.S. dollar. For purposes of preparing our financial statements, these amounts are converted into U.S. dollars, the value of which varies with currency exchange rate fluctuations. For sales 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 results of operations. Although we address currency risk management through regular operating and financing activities, those actions may not prove to be fully effective.

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 CoCr used in certain of our hip, shoulder and elbow products. Establishing additional or replacement suppliers for these components, and obtaining regulatory clearance 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, we do not believe that any such failure would result in a material adverse effect on our business, particularly because these suppliers do not, individually or in the aggregate, represent a material portion of our business. We may also have 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

Table of Contents

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 must also 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;
- 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;
- increased competition;
- the timing and extent of promotional pricing or volume discounts;
- the availability and cost of components and materials;
- the number of selling days;
- fluctuations in foreign currency exchange rates; 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 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;

Table of Contents

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.

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 deny or require a significant narrowing of the claims in our pending patent applications and 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 can 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 priority of our inventions and the narrowing or invalidation 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 upon 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 results of operations.

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

Table of Contents

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 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.

We have received, and we may receive in the future, notifications of potential conflicts of existing patents, pending patent applications and challenges to the validity of existing patents. For example, we corresponded with DePuy in 2006 regarding a possible license granted by DePuy to us under a French patent in connection with one of our shoulder products. We did not come to any agreement with DePuy and last corresponded on this matter in early 2007. We were contacted by an individual in June 2010 regarding his French patent and his request that we explain our position regarding this patent with respect to our hip product Meije Duo. We analyzed the patent and our product and responded to the individual stating our belief the product falls outside the scope of his patent. The individual has not responded. We have searched and found that the individual has no corresponding patent outside of

Table of Contents

France. We do not believe that either notification will have a material adverse effect on our future business. In addition, we may, in the future, become aware of patent applications and issued patents that relate to our products or the surgical applications using our products and, in some cases, we may discuss with outside counsel the relevance of such issued patents to our products.

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. We continue to emphasize the development of proprietary products and product improvements to complement and expand our existing product lines. If we are unable to maintain these relationships, our ability to market 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, which can reduce our cash flows.

As a result of the need to maintain substantial levels of inventory, we are subject to the risk of inventory obsolescence. The nature of our business requires us to maintain a substantial level of inventory. For example, our total consolidated inventory balances were \$77.5 million and \$68.6 million at January 2, 2011 and December 27, 2009, respectively. 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.

Recent acquisitions and efforts to acquire and integrate other companies or product lines could adversely affect our operations and financial results.

We may pursue 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 future acquisitions, we may experience:

difficulties in integrating any acquired companies, personnel and products into our existing business;

delays in realizing the benefits of the acquired company or 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;

higher costs of integration than we anticipated; or

difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

In addition, any future acquisitions could materially impair our operating results by causing us to incur debt or requiring us to amortize acquired assets.

Table of Contents

If we cannot retain our key personnel, we will 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 business 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, strikes our manufacturing facilities or distribution channels, we could be unable to manufacture or distribute our products for a substantial amount of time and our sales could decline.

We principally rely on five manufacturing facilities, three of which are in France and two of which are 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 warehouses in Stafford, Texas and Montbonnot, France, containing 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 hurricane in Stafford, Texas, 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 sales 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.

Recent turmoil in the credit markets and the financial services industry may negatively affect our business.

Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from U.S. and foreign governments. While the ultimate outcome of these events cannot be predicted, they may have an adverse effect on our customers' ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products. In addition, the recent economic crises could also

Table of Contents

adversely affect our suppliers' ability to provide us with materials and components, either of which may negatively impact our business.

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:

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 existing cash and cash equivalent balances and cash receipts generated from sales of our products, will be sufficient to meet our anticipated cash requirements for the foreseeable future. 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 and timing of additional regulatory clearances or approvals;

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

Edgar Filing: Tornier N.V. - Form 10-K

the effect of competing technological and market developments; and

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

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. 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.

Table of Contents

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. 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 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 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.

Our outstanding debt agreements contain restrictive covenants that may limit our operating flexibility.

The agreements relating to our outstanding debt contain some financial 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 and conduct transactions with affiliates. We therefore may not be able to engage in any of the foregoing transactions 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 the 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.

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

In the United States, healthcare providers who purchase our products generally rely on third-party payors, 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 sales depend 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 implants as experimental or investigational and denied coverage and reimbursement for such procedures. Surgeons, hospitals and other healthcare providers may not

Table of Contents

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 sales 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.

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 sales and results of operations.

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 results of operations.

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 and will likely 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 results of operations.

Table of Contents

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. 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. 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. In the event we experience significant disruptions as a result of the current implementation in our 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 results of operations 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 approvals and clearances, 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;

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

Table of Contents

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 clearance 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 sales 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.

Any delay in, or failure to receive or maintain, clearance or approval 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;

Table of Contents

recalling, detaining or seizing our products; or

withdrawing or denying approvals or clearances for our products.

If we fail to obtain and maintain regulatory approvals or clearances, our ability to sell our products and generate revenues 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.

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, results of operations 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

Table of Contents

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 the recently enacted legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, which 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.

These provisions could meaningfully change the way healthcare is delivered and financed, and may materially impact numerous aspects of our business.

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 results of operations.

Additionally, 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

Table of Contents

increase in the tax burden on our industry, which could have a material, negative impact on our results of operations 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 such promotion.

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, however, 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, it 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 might also 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.

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 may also 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 results of operations.

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 may, on their own initiative, 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 results of operations. 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 may also be required to bear other costs or take other actions that may have a negative impact on our future sales 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

Table of Contents

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 sales. 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.

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 are also 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

Table of Contents

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 may also be required to bear other costs or take other actions that may have a negative impact on our future sales 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.

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 could also 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 sales to suffer and may prevent us from generating revenue.

Table of Contents

The results of our clinical trials may not support our product candidate 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 of 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 candidate 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 product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate 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 product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

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.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

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

Table of Contents

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

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 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 will also 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

Table of Contents

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 may also 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, results of operations and cash flows.

Failure to obtain and maintain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We currently market, and intend to continue to market, our products internationally. 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 foreign regulatory approval process 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 foreign regulatory approvals or certifications 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 foreign 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

Table of Contents

necessary approvals to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, financial condition and results of operations 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.

While we do not currently offer any products based on human tissue, in the future we may offer biologics 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.

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 are also 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 allogeneic 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

Table of Contents

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 for processing. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby 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 results of operations. 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.

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 are also 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,

Table of Contents

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.

Risks Relating to Our Ordinary Shares

The trading prices of our ordinary shares are likely to be volatile, which could result in substantial losses to investors.

The trading prices of our ordinary shares are likely to be volatile and could fluctuate widely due to factors beyond our control. 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. A number of European companies have listed or are in the process of listing their securities on U.S. stock markets. The securities of some of these companies have experienced significant volatility, including price declines in connection with their initial public offerings. The trading performances of these European companies' securities after their offerings may affect the attitudes of investors toward European companies listed in the United States in general and consequently may impact the trading performance of our ordinary shares, regardless of our actual operating performance.

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;

release of lock-up or other transfer restrictions on our outstanding equity securities or sales of additional equity securities;

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 will 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 results of operations 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

Table of Contents

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 results of operations.

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 2009, we identified a material weakness in our internal control over financial reporting relating to our audited financial statements for fiscal years 2007 and 2008. Specifically, in our case, management and our independent registered accounting firm have 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 implemented initiatives aimed at addressing this material weakness, these initiatives may not remediate the identified material weakness. Our management and independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act. As a public company, absent an available exemption, we will be required to comply with Section 404 of the Sarbanes-Oxley Act by no later than December 31, 2011. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. We cannot be certain as to when we will be able to implement the requirements of Section 404 of the Sarbanes-Oxley Act. If we fail to implement the requirements of Section 404 in a timely manner, we might be subject to sanctions or investigation by regulatory agencies such as the SEC. In addition, failure to comply with Section 404 or the 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 will be 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 would likely 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.

Table of Contents

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 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., or VFI, Vertical Fund II, L.P., or VFII, KCH Stockholm AB, or KCH, Phil Invest ApS and Douglas W. Kohrs, which requires us to register up to 27,590,201 of our ordinary shares held by these persons under the Securities Act, subject to certain restrictions and conditions described in "Description of Ordinary Shares Registration Rights". The market price of our ordinary shares could decline as a result of the registration of or the perception that registration may occur of a large number of our ordinary shares.

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 will be 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 annual report are not residents of the United States, and certain of our directors and our 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.

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.

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

Table of Contents

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 the board of directors may deem relevant.

WP Bermuda and its affiliates, a significant shareholder, control approximately 47% of our ordinary shares, and this concentration of ownership may have an effect on transactions that are otherwise favorable to our shareholders.

WP Bermuda and its affiliates, or Warburg Pincus, beneficially own, in the aggregate, approximately 47% 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 may also delay, deter or prevent a change in control, and 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our U.S. headquarters are located in a 19,100 square foot facility in Edina, Minnesota, where we conduct our principal executive, sales and marketing and administrative activities. This facility is leased through 2015. Our U.S. distribution and customer service operations are based in an owned 20,000 square foot facility in Stafford, Texas and our research and development operations are based in a 12,200 square foot leased facility in Warsaw, Indiana, with small satellite quality, marketing and research and development offices in Beverly, Massachusetts and San Diego, California.

Our global corporate headquarters are located in Amsterdam, the Netherlands. Outside the United States, our primary manufacturing facilities are in Montbonnot, Saint-Ismier and Grenoble, France; and Dunmanway and Macroom, Ireland. In the 112,000 square foot Montbonnot campus, we conduct manufacturing, sales and marketing, research and development, quality and regulatory assurance, distribution and administrative functions. In our 54,900 square foot Saint-Ismier facility and 15,200 square foot Dunmanway and 84,700 square foot Macroom facilities, we conduct manufacturing operations and manufacturing support such as purchasing, engineering and quality assurance functions. Our pyrocarbon manufacturing is performed at our 9,900 square foot facility in Grenoble, France. In addition, we maintain subsidiary sales offices and distribution warehouses in various countries, including France, Germany, Italy, the Netherlands, Denmark, Spain, Switzerland, United Kingdom and Australia. We believe that our facilities are adequate and suitable for their use.

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Below is a summary of our material facilities:

Entity	City	State/Country	Owned or Leased	Occupancy	Square Footage	Lease Expiration Date
Tornier, Inc.	Stafford	Texas, United States	Owned	Offices/Warehouse/Distribution	20,000	N/A
Tornier, Inc.	Warsaw	Indiana, United States	Leased	Offices/R&D	12,200	2/28/2015
Tornier, Inc.	Edina	Minnesota, United States	Leased	Offices	19,100	12/31/2015
Tornier SAS	St Ismier	France	Leased	Offices/Manufacturing/Warehouse/Distribution	54,900	5/29/2012
Tornier SAS	Montbonnot	France	Leased	Offices	15,100	5/29/2012
Tornier SAS	Montbonnot	France	Leased	Warehouse/Distribution/Offices	19,500	5/29/2012
Tornier SAS	Montbonnot	France	Leased	Offices/R&D	25,500	5/29/2012
Tornier SAS	Montbonnot	France	Owned 51%	Manufacturing/Offices	51,700	9/3/2018
Tornier SAS	Grenoble	France	Leased	Manufacturing/Offices/R&D	9,900	7/22/2012
Tornier Deutschland GmbH	Burscheid	Germany	Owned	Sales Office	1,900	N/A
Tornier Orthopedics Ireland Limited	Dunmanway	Ireland	Owned	Manufacturing/Offices	15,200	N/A
Tornier Orthopedics Ireland Limited	Macroom	Ireland	Leased	Manufacturing/Offices	84,700	12/1/2028
Tornier N.V.	Schiedam	The Netherlands	Leased	Offices	720	10/31/2012

Item 3. Legal Proceedings.

On October 25, 2007, two of our former sales agents filed a complaint in the U.S. District Court for the Southern District of Illinois, alleging that we had breached their agency agreements and committed fraudulent and negligent misrepresentations. The plaintiffs, Garry Boyd of Boyd Medical, Inc. and Charles Wetherill of Addison Medical, Inc., claimed that we had intentionally set their 2007 quotas too high, in hopes that Messrs. Boyd and Wetherill would not meet the quotas so that we could terminate them for cause and install another distributor in their territories. The complaint also included allegations that we had falsely suggested to the plaintiffs that if they dropped all other product lines, we would fill the void with new product lines. The jury rendered a verdict on July 31, 2009, awarding the plaintiffs a total of \$2.6 million in actual damages and \$4 million in punitive damages. While the court struck the award of punitive damages on March 31, 2010, it denied our motion to set aside the verdict or order a new trial. We have filed a notice of appeal with the U.S. Court of Appeals for the Seventh Circuit in respect of the remaining actual damages.

On July 7, 2010, the Company submitted its opening brief to the United States Court of Appeals for the Seventh Circuit. The Plaintiffs filed their opening briefs during August 2010. The consolidated appeal has been argued before the U.S. Court of Appeals for the Seventh Circuit. We expect a decision in the first half of 2011.

Table of Contents

We have considered the facts of the case and related case law and, based on this information, we believe that the verdict rendered on July 31, 2009 was inappropriate given the related facts and supporting legal arguments. We have been successful in striking the jury awarded punitive damages through a motion filed with the original court. We have filed a notice of appeal with the U.S. Court of Appeals for the Seventh Circuit in respect of the remaining actual damages. We have considered the progress of the case, the views of legal counsel and the facts and arguments presented at the original jury trial and the fact that we intend to vigorously defend our position through the appellate courts in assessing the probability of a loss occurring for this matter. We believe we must assess the probability of the incurrence of a loss, and the ability to reasonably estimate such loss, based on the possible outcomes of the entire legal process including the appeals process. We believe our legal appeal is strong and that the range of possible outcomes is between zero and \$6.6 million. After assessing all relevant information, we do not believe there to be a reasonably estimable loss within the range of possible outcomes that is probable of occurring. As a result, we have not recorded an accrual for any loss related to this issue. We have determined that a loss is reasonably possible, and management estimates the range of loss to be between zero and \$6.6 million, the amount of the initial jury verdict. We believe we have a strong defense against these claims and are vigorously contesting these allegations. As of January 2, 2011, no accrual was recorded relating to this case.

In addition to the item noted above, we are subject to various other legal proceedings, product liability claims and other matters which arise in the ordinary course of business. In the opinion of management, the amount of liability, if any, with respect to these matters will not materially affect our consolidated results of operations or financial position.

Item 4. (Removed and Reserved).

Table of Contents

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ordinary shares began trading on February 3, 2011 on the NASDAQ Global Select Market under the symbol "TRNX" in connection with our initial public offering. Prior to that, there was no public market for our ordinary shares.

Holders

As of January 2, 2011 there were 13 shareholders of record.

Dividends

We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our ordinary shares in the foreseeable future. Any payment of cash dividends on our ordinary shares will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors.

Purchases of Equity Securities by the Company

None.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

Our initial public offering, or the Offering, was effected through a Registration Statement on Form S-1 (File No. 333-167370) that was declared effective by the SEC on February 2, 2011. An aggregate of 10,062,500 ordinary shares were registered (including the underwriters' over-allotment of 1,312,500 ordinary shares), of which we sold 8,750,000 shares, at an initial price to the public of \$19.00 per share (before underwriters' discounts and commissions). The Offering closed on February 8, 2011, and, as a result, we received net proceeds of approximately \$155.4 million (after underwriters' discounts and commissions of approximately \$10.8 million, but before additional offering related costs). Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC were the managing underwriters of the Offering. Subsequently, on March 7, 2011, we issued an additional 721,274 ordinary shares at an offering price of \$19.00 per share (before underwriters' discounts and commissions) due to the exercise of the underwriters' overallotment option. We received proceeds of approximately \$12.8 million (after underwriters' discounts and commissions of approximately \$0.9 million).

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

In February 2011, we used approximately \$116.1 million of the net proceeds from the offering to repay all of the outstanding indebtedness under our notes payable, including accrued interest thereon, payable of approximately €86.4 million. We expect to use the remaining net proceeds for general corporate purposes. Pending the uses described above, we intend to invest the net proceeds in a variety of short-term, interest-bearing, investment grade securities. There has been no material change in the

Table of Contents

planned use of proceeds from the Offering from that described in the final prospectus dated February 2, 2011 filed by us with the SEC pursuant to Rule 424(b)(1).

Equity Compensation Plan Information

As of January 2, 2011, our equity compensation plan information was as follows:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (in thousands) (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (in thousands, excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,532	\$ 17.02	1,200
Equity compensation plans not approved by security holders	0	0	0
Total	3,532	\$ 17.02	1,200

Item 6. Selected Financial Data.

The following tables set forth certain of our selected consolidated financial data as of the dates and for the years indicated. The selected consolidated financial data was derived from our consolidated financial statements audited by Ernst & Young LLP. The audited consolidated financial statements as of January 2, 2011, December 27, 2009 and December 28, 2008, and for the years then ended, are included elsewhere in this annual report. The audited consolidated financial statements as of December 31, 2007 and December 31, 2006 and for the periods then ended, are not included in this

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

filing. Historical results are not necessarily indicative of the results to be expected for any future period. These tables are presented in thousands, except per share data.

	Year ended				Period from July 18, 2006 to December 31, 2006
	January 2, 2011	December 27, 2009	December 28, 2008	December 31, 2007	
(in thousands, except per share data)					
Statement of Operations Data:					
Revenue	\$ 227,378	\$ 201,462	\$ 177,370	\$ 145,369	\$ 46,158
Cost of goods sold	63,437	54,859	45,500	46,573	19,912
Gross profit	163,941	146,603	131,870	98,796	26,246
Sales and marketing	126,809	115,630	106,870	82,014	21,544
General and administrative	22,366	20,790	21,742	17,976	9,118
Research and development	17,896	18,120	20,635	13,305	1,730
Amortization of intangible assets	11,492	15,173	11,186	7,946	2,272
Special charges	306	1,864			
In-process research and development				15,107	9,649
Operating loss	(14,928)	(24,974)	(28,563)	(37,552)	(18,067)
Interest expense	(21,582)	(19,667)	(11,171)	(2,394)	(828)
Foreign currency transaction gain (loss)	(8,163)	3,003	1,701	(5,859)	115
Other non-operating (expense) income	43	(28,461)	(1,371)	(1,966)	
Loss before income taxes	(44,630)	(70,099)	(39,404)	(47,771)	(18,780)
Income tax benefit	5,121	14,413	5,227	6,580	2,279
Consolidated net loss	(39,509)	(55,686)	(34,177)	(41,191)	(16,501)
Net loss attributable to noncontrolling interest	(695)	(1,067)	(1,173)		
Net loss attributable to Tornier	(38,814)	(54,619)	(33,004)	(41,191)	(16,501)
Accretion of noncontrolling interest	(679)	(1,127)	(3,761)		
Net loss attributable to ordinary shareholders	\$ (39,493)	\$ (55,746)	\$ (36,765)	\$ (41,191)	\$ (16,501)
Weighted-average ordinary shares outstanding: basic and diluted	27,770	24,408	23,930	22,222	14,667
Net loss per share: basic and diluted	\$ (1.42)	\$ (2.28)	\$ (1.54)	\$ (1.85)	\$ (1.13)
Balance Sheet Data:					
Cash and cash equivalents	24,838	\$ 37,969	\$ 21,348	\$ 17,347	\$ 8,734
Other current assets	148,376	133,179	122,167	107,968	88,911
Total assets	491,178	520,187	475,967	431,614	291,124
Total liabilities	220,939	277,140	212,442	181,738	141,426
Noncontrolling interest		23,259	23,200		
Total shareholders' equity	270,239	219,788	240,325	249,876	149,698
Other Financial Data:					
Net cash provided by (used in) operating activities	\$ 2,889	\$ 2,291	\$ (19,482)	\$ (8,165)	\$ 6,116

Edgar Filing: Tornier N.V. - Form 10-K

Net cash provided by (used in) investing activities	(22,853)	(31,104)	(43,314)	(106,188)	(14,508)
Net cash provided by (used in) financing activities	7,427	44,857	66,487	121,886	(1,829)
Depreciation and amortization	27,038	29,732	22,331	15,582	4,919
Capital expenditures	20,525	(23,448)	(31,622)	(17,729)	(4,671)
Effect of exchange rate changes on cash and cash equivalents	(594)	577	310	1,080	699

58

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations together with the selected consolidated financial data, consolidated financial statements and the notes thereto included elsewhere in this annual report, and other financial information included in this annual report. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this annual report. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

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 80 product lines in approximately 35 countries.

We have had a tradition of innovation, intense focus on surgeon education and commitment to advancement of orthopaedic technology since our founding approximately 70 years ago in France by René Tornier. Our history includes the introduction of the porous orthopaedic hip implant, the application of the Morse taper, which is a reliable means of joining modular orthopaedic implants, and, more recently, the introduction of the reversed shoulder implant in the United States. This track record of innovation over the decades stems from our close collaboration with leading orthopaedic surgeons and thought leaders throughout the world.

We were acquired in 2006 by the Investor Group, who recognized the potential to leverage our reputation for innovation and our strong extremity joint portfolio as a platform upon which they could build a global company focused on the rapidly evolving upper and lower extremity specialties. The Investor Group has contributed capital resources and a management team with a track record of success in the orthopaedic industry in an effort to expand our offering in extremities and accelerate our growth. Since the acquisition in 2006, we have:

created a single, extremity specialist sales channel in the United States primarily focused on our products;

enhanced and broadened our portfolio of shoulder joint implants and foot and ankle products;

entered the sports medicine and biologics markets through acquisitions and licensing agreements;

improved our hip and knee product offerings, helping us gain market share internationally; and

significantly increased investment in research and development and expanded business development activities to build a pipeline of innovative new technologies.

We believe we are differentiated by our full portfolio of upper and lower extremity products, our dedicated 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 already among the global leaders in the shoulder and ankle joint replacement markets. We more recently have expanded our technology base and product offering to include: new joint replacement products based on new materials; improved trauma products based on innovative designs; and proprietary orthobiologic materials for soft tissue repair. In the United States, which is the largest orthopaedic market, we believe that our single, "specialists serving specialists" distribution

Table of Contents

channel 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 products include joint replacement and bone fixation devices for the shoulder, hand, wrist and elbow. Our lower extremity 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 mechanically repair tissue-to-tissue or tissue-to-bone injuries, in the case of sports medicine, or to support or induce remodeling and regeneration of tendons, ligaments, bone and cartilage, in the case of biologics. Our large joints and other products include hip and knee joint replacement implants and ancillary products.

Innovations in the orthopaedic industry have typically consisted of evolutions of product design in implant fixation, joint mechanics, and instruments and modifications of existing metal or plastic-based device designs rather than new products based on combinations of new designs and new materials. In contrast, the growth of our target markets has been driven by the development of products that respond to the particular mechanics of small joints and the importance of soft tissue to small joint stability and function. We are committed to the development of new designs utilizing both conventional materials and new tissue-friendly biomaterials that we expect will create new markets. We believe that we are a leader in researching and incorporating some of these new technologies across multiple product platforms.

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 nor do we currently have plans to do so. While we market our products to extremity specialists, our revenue is generated from sales to healthcare institutions and distributors. We sell through a single sales channel consisting of a network of independent commission-based sales agencies. Internationally, where the trend among surgeons toward specialization is not as advanced as in the United States, 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 independent distributors for most other international markets. In 2010, we generated revenue of \$227.4 million, 56% of which was in the United States and 44% of which was international.

We have significantly grown our business since our acquisition by the Investor Group in July 2006. Since then we have built an extremities focused business that offers a broad range of products to a focused group of specialty surgeons. We believe this strategy has been the primary factor in enabling our revenue growth from 2006 to 2010. During that time we also increased our operating expenses significantly. We have strategically invested with particular emphasis on product development, acquisition of strategic products and technologies and sales commissions to support both current and future growth. While we experienced operating losses during 2010, we also believe the investments made will allow us to grow our revenue at rates exceeding our expected growth in operating expenses in the future.

Foreign Currency Exchange Rates

A substantial portion of our business is located outside the United States and as a result we generate revenue and incur expenses denominated in currencies other than the U.S. dollar. The majority of our operations denominated in currencies other than the U.S. dollar are denominated in Euros. In 2010, 2009 and 2008, approximately 44%, 44% and 49%, respectively, of our sales were denominated in foreign currencies. As a result, our revenue can be significantly impacted by

Table of Contents

fluctuations in foreign currency exchange rates. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Selling, marketing and administrative costs related to these sales are largely denominated in the same foreign currencies, thereby limiting our foreign currency transaction risk exposure. We therefore believe that the risk of a significant impact on our earnings from foreign currency fluctuations is mitigated. However, a substantial portion of the products we sell in the United States are manufactured in countries where costs are incurred in Euros. Fluctuations in the Euro to U.S. dollar exchange rate will have an impact on the cost of the products we manufacture in those countries, but we would not likely be able to change our U.S. dollar selling prices of those same products in the United States in response to those cost fluctuations. As a result, fluctuations in the Euro to U.S. dollar exchange rates could have a significant impact on our gross profit in the future.

Basis of Presentation

Our fiscal year-end is generally determined on a 52-week basis and always falls on the Sunday nearest to December 31. Every few years, it is necessary to add an extra week to the year making it a 53-week period in order to have our year end fall on the Sunday nearest to December 31. For example, the year ended January 2, 2011 includes an extra week of operations relative to the years ended December 27, 2009 and December 28, 2008. For purposes of this management's discussion and analysis of financial condition and results of operations, references to:

2010 and our 2010 fiscal year refer to the fiscal year ended January 2, 2011;

2009 and our 2009 fiscal year refer to the fiscal year ended December 27, 2009;

2008 and our 2008 fiscal year refer to the fiscal year ended December 28, 2008;

Recent Acquisitions

C2M Medical, Inc., or C2M Medical. On March 26, 2010, we exercised our option to acquire 100% of the stock of C2M Medical, a medical device development company based in San Antonio, Texas, focused on the sports medicine market. C2M Medical developed the Piton Knotless Anchor, an advanced arthroscopic technology for rotator cuff repair. In 2008, we signed a license agreement with C2M Medical for exclusive worldwide rights to the Piton, along with an option to acquire the company. C2M Medical was determined to be a variable interest entity and was consolidated by us beginning in 2008 upon signing the initial license agreement. Refer to Note 14 of our consolidated financial statements for further information regarding the accounting for C2M Medical.

Revenue

We derive our revenue from the sale of medical devices that are used by surgeons who treat diseases and disorders of extremity joints including the shoulder, elbow, wrist, hand, ankle and foot. We report our sales in four primary product categories: upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics, and large joints and other. Our revenue is generated from sales to two types of customers: healthcare institutions and distributors, with healthcare institutions representing a majority of our revenue. We utilize a network of independent sales agencies for sales in the United States and a combination of employee sales representatives, independent sales agencies and distributors for sales outside the United States. Revenue from sales to healthcare institutions is recognized at the time of surgical implantation. We generally record revenue from sales to our distributors at the time the product is shipped to the distributor. Distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at the time of shipment. Our distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. We charge our customers for shipping and record shipping revenue as part of revenue.

Table of Contents

Cost of Goods Sold

We manufacture a majority of the products that we sell. Our cost of goods sold consists primarily of direct labor, allocated manufacturing overhead, raw materials and components, and excludes amortization of intangible assets, which is presented as a separate component of operating expenses. A portion of the products we sell are manufactured by third parties, and our cost of goods sold for those products consists primarily of the price invoiced by our third-party vendors. Cost of goods sold also includes share-based compensation expenses related to individuals whose salaries are also included within this category. A majority of our current manufacturing facilities are located in Europe and the related manufacturing costs are incurred in Euro. As a result, the cost of goods sold for our products sold in the United States that were manufactured in Europe is subject to foreign currency exchange rate fluctuations.

Sales and Marketing

Our variable selling costs consist primarily of commissions paid to our independent sales agencies used in the United States and some other countries to generate sales, royalties based on certain product sales and freight expense we pay to ship our products to customers. Our non-variable sales and marketing costs consist primarily of salaries, personnel costs, including share-based compensation and other support costs related to the selling, marketing and support of our products as well as trade shows, promotions and physician training. Sales and marketing expenses also include the cost of distributing our products, which includes the operating costs and certain administrative costs related to our various worldwide sales and distribution operations. We provide surgical instrumentation to our customers for use during procedures involving our products. There are no contractual arrangements related to our customers' use of our surgical instrumentation and we do not charge a fee for providing access to the related instrumentation. We record surgical instrumentation on our balance sheet as a long-lived asset. The depreciation expense related to our surgical instrumentation is included in sales and marketing expenses.

General and Administrative

General and administrative expenses consist of expenses for our executive, finance, legal, compliance, administrative, information technology and human resource departments. General and administrative expenses also include share-based compensation expense related to individuals within these departments.

Research and Development

Research and development expenses include costs associated with the design, development, testing, deployment and enhancement of products and certain regulatory costs. This category also includes costs associated with the design and execution of our clinical trials and regulatory submissions. Research and development expenses also include share-based compensation related to individuals within our research and development groups.

Amortization of Intangible Assets

Amortization expense for intangible assets includes purchased developed technology, customer relationships and intellectual property, including patents and license rights.

Special Charges

Special charges consist of certain severance, lease termination and moving costs related to the consolidation of our U.S. facilities during 2009 and 2010. Special charges also include legal and

Table of Contents

consulting costs related to establishing new sales and distribution subsidiaries in the United Kingdom and Denmark.

Interest Expense

Interest expense reflects interest associated with both our notes payable and other long-term and short-term debt. Our notes payable accrue paid-in-kind interest at a rate of 8% annually. Our notes payable were also issued together with warrants to purchase our ordinary shares. The estimated fair value of the warrants at the date of issuance was recorded as a discount to the related notes payable. The debt discount is accreted as additional interest expense to the par value of the notes payable over the related term. We also incur interest expense at varying rates of interest on various revolving lines of credit, secured and unsecured term loans and other mortgage-related debt.

Foreign Currency Transaction Gain (Loss)

Foreign currency transaction gain (loss) consists primarily of foreign currency gains and losses on transactions denominated in a currency other than the functional currency of the related entity. Our foreign currency transactions primarily consist of foreign currency denominated cash, liabilities and intercompany receivables and payables.

Other Non-operating (Expense) Income

Other non-operating (expense) income primarily relates to losses incurred in the revaluation of our warrant liabilities to fair value as well as other expenses not related to the operations of the business.

Income Tax Benefit

Income tax benefit includes federal income taxes, income taxes in foreign jurisdictions, state income taxes and changes to our deferred taxes and deferred tax valuation allowance.

Results of Operations***Fiscal Year Comparisons***

The following table sets forth, for the periods indicated, our results of operations expressed as a percentage of revenue.

	January 2, 2011	Year ended December 27, 2009	December 28, 2008
Revenue	100%	100%	100%
Cost of goods sold	28	27	26
Gross profit	72	73	74
Operating expenses:			
Selling and marketing	56	57	60
General and administrative	10	10	12
Research and development	8	9	12
Amortization of intangible assets	5	8	6
Special charges		1	
Operating loss	(7)%	(12)% 63	(16)%

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

The following tables set forth, for the periods indicated, our revenue by product category and geography expressed as dollar amounts and the changes in revenue between the specified periods expressed as percentages:

Revenue by Product Category

	January 2, 2011	Year ended December 27, 2009	December 28, 2008	2010/ 2009	Percent change 2009/ 2008	2010/ 2009 (constant currency)	2009/ 2008
	(\$ in thousands)			(as stated)			
Upper extremity joints and trauma	\$ 139,175	\$ 125,454	\$ 108,829	11%	15%	11%	17%
Lower extremity joints and trauma	23,629	20,417	18,167	16%	12%	16%	13%
Sports medicine and biologics	13,210	6,593	2,513	100%	162%	101%	162%
Total extremities	176,014	152,464	129,509	15%	18%	16%	18%
Large joints and other	51,364	48,998	47,861	5%	2%	9%	7%
Total	\$ 227,378	\$ 201,462	\$ 177,370	13%	14%	14%	16%

Revenue by Geography

	January 2, 2011	Year ended December 27, 2009	December 28, 2008	2010/ 2009	Percent change 2009/ 2008	2010/ 2009 (constant currency)	2009/ 2008
	(\$ in thousands)			(as stated)			
United States	\$ 127,762	\$ 112,588	\$ 91,106	13%	24%	13%	24%
International	99,616	88,874	86,264	12%	3%	15%	8%
Total	\$ 227,378	\$ 201,462	\$ 177,370	13%	14%	14%	16%

Fiscal Year Ended January 2, 2011 Compared to Fiscal Year Ended December 27, 2009

Revenue. Revenue increased by 13% to \$227.4 million in 2010 from \$201.5 million in 2009 as a result of increased sales in each of our product categories, with the most significant dollar increase occurring in our upper extremity joints and trauma category. Fiscal year 2009 included a revenue reversal of approximately \$1.3 million related to the repurchase of inventory from a stocking distributor in 2009 that was terminated as part of our launch of a direct sales subsidiary in the United Kingdom. We have also experienced an increase in sales in our sports medicine and biologics categories as we continue to focus on our distribution efforts in this market. Our overall revenue growth of 13% consisted of 13% growth in the United States and 12% growth in our international geographies. Our revenue was negatively impacted by foreign currency fluctuations of approximately \$2.8 million during 2010. Revenue also increased over 2009 due to five extra selling days of operations included in 2010. Our global revenue growth, excluding the impact of foreign currency fluctuations for 2010, was 14%.

Revenue by product category. Revenue in upper extremity joints and trauma product category increased by 11% to \$139.2 million in 2010 from \$125.5 million in 2009 primarily as a result of the continued increase in sales of our Aequalis, Affiniti and Ascend shoulder products. We believe that increased sales of our Aequalis shoulder resulted from continued market growth in shoulder replacement procedures and further market acceptance of our reversed shoulder joint replacement products. We have also seen an increase in sales in our Affiniti shoulder products, which were launched at the end of 2008. Revenue in our lower extremity joints and trauma increased by 16% to \$23.6 million for 2010 from \$20.4 million for 2009, primarily due to increased sales in our foot and

Table of Contents

ankle fixation products in both the United States and internationally. We continue to focus our U.S. distribution network on selling our full range of products and have increased the number of products available internationally. Revenue in sports medicine and biologics increased by 100% to \$13.2 million for 2010 from \$6.6 million for 2009. This increase was attributable to an increase in sales of our Piton products, as well as an increase in sales of our Conexa product, which was in initial launch during the first quarter of 2009. Fiscal year 2010 also included revenue from our ArthroTunneler, which was launched during the second half of 2009. Revenue from large joints and other increased by 5% to \$51.4 million for 2010 from \$49.0 million for 2009. Our large joint and other revenue increase was primarily due to an increased level of sales to international stocking distributors as we continue to expand our geographic footprint, continued growth of our core hip products internationally and the existence of an extra week in 2010, offset by approximately \$2.2 million of unfavorable impacts from changes in foreign currency exchange rates.

Revenue by geography. Revenue in the United States increased by 13% to \$127.8 million in 2010 from \$112.6 million in 2009, primarily driven by continued increase in sales in upper extremities joints and trauma products, together with a significant increase in sales in sports medicine and biologics products with the launch of Conexa and the ArthroTunneler and as our distribution focus on this category increased. Revenue from 2010 was also favorably impacted by the extra week during the year compared to 2009. International revenue increased by 12% to \$99.6 million in 2010 from \$88.9 million in 2009. Our international revenue was negatively impacted by approximately \$2.8 million in 2010 as a result of foreign currency fluctuations, principally due to the performance of the Euro against the U.S. dollar. Excluding the impact of the change in currency exchange rates, our international revenue increased by 15% in 2010, primarily due to the launch of our United Kingdom sales office in the first quarter of 2010, increased revenue in France, Spain, and Australia, and the existence of an extra fiscal week in 2010. Fiscal year 2009 was also negatively impacted by approximately \$1.3 million from the repurchase of inventory previously discussed.

Cost of goods sold. Our cost of goods sold increased by 16% to \$63.4 million in 2010 from \$54.9 million in 2009. As a percentage of revenue, cost of goods sold increased to 28% in 2010 from 27% in 2009. We have intentionally increased our manufacturing overhead costs in an effort to establish a sufficient level of capacity and manufacturing infrastructure to support our current and future growth plans. Our manufacturing overhead costs have grown at a rate faster than our factory output in recent years, causing an increase in the fully absorbed cost of our products. However, we believe this has allowed us to establish an infrastructure that will be able to sustain our sales growth and has increased our ability to leverage our costs in the future. Our gross profit as a percentage of revenue was impacted by a change in relative mix of our fourth quarter revenue between our European distributor business and our U.S. business, resulting in less high-margin sales in the United States, as a percentage of total sales, and more low-margin sales from certain stocking distributors. This impact was partially offset by a lower level of inventory obsolescence. Our cost of goods sold and corresponding gross profit as a percentage of revenue can be expected to fluctuate in future periods depending upon changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses, levels of production volume and currency exchange rates.

Selling and marketing. Our selling and marketing expenses increased by 10% to \$126.8 million in 2010 from \$115.6 million in 2009, primarily as a result of \$5.3 million of additional variable commissions and royalty expenses on higher revenue, and approximately \$1.4 million of increased non-variable selling and marketing expenses related to the additional week of operations included in the first quarter of 2010, offset by approximately \$1.1 million of decreased expense due to changes in foreign currency exchange rates. The remaining increase in selling and marketing expenses relates to general increases in our selling, marketing, training and distribution costs to support continued growth and product expansion, including our direct expansion into the United Kingdom and Scandinavia. Selling and marketing expense as a percentage of revenue decreased from 57% for 2009 to 56% for

Table of Contents

2010. The decrease in our selling and marketing expenses as a percentage of revenue is due primarily to revenue growing at a faster rate than our non-variable selling expenses.

General and administrative. Our general and administrative expenses increased by 8% to \$22.4 million in 2010 from \$20.8 million in 2009. As a percentage of revenue, general and administrative expenses remained at 10% for 2010 and 2009. The increase in expenses in 2010 is primarily due to severance-related expenses of approximately \$0.4 million recognized in the first quarter of 2010 from the departure of our former CFO, as well as increased stock option expense of approximately \$0.6 million. The remaining increase in general and administrative expenses relates to increased information technology, legal, tax and accounting expenses as we continued to prepare ourselves to be a publicly traded company.

Research and development. Research and development expenses decreased by 1% to \$17.9 million in 2010 from \$18.1 million in 2009, primarily due to a \$0.2 million favorable impact from foreign currency exchange rate fluctuations. Research and development expenses were also impacted by a reduction in the required outside spending for the particular product development projects underway during 2010 as compared to 2009, as well as a \$0.3 million research grant given to the Orthopedic Research and Education Foundation during 2009 that did not recur in 2010. This decrease in product development expenses was offset by consolidated operating expenses from C2M Medical, including certain operating expenses related to the launch of our Piton product. C2M Medical was a variable interest entity which we consolidated in 2008 and which holds the intellectual property related to our Piton products. Fiscal year 2010 included \$0.6 million of operating expenses related to C2M Medical compared to an immaterial amount for 2009. During the first quarter of 2010, we acquired C2M Medical and merged the entity into our existing U.S. operations. The acquisition of C2M was completed in order to purchase the intellectual property related to our Piton products, which we had previously been licensing from C2M, and therefore the C2M entity was no longer needed. As a percentage of revenue, research and development decreased from 9% for 2009 to 8% for 2010. We expect our level of research and development to fluctuate depending on the timing of new product development projects and clinical study costs.

Amortization of intangible assets. Amortization of intangible assets decreased by 24% to \$11.5 million in 2010 from \$15.2 million in 2009, primarily due to a \$3.4 million impairment loss recognized in the fourth quarter of 2009 when developed technology from certain acquired entities was abandoned. There were no intangible asset impairments recognized during 2010.

Special charges. Special charges decreased by 84% to \$0.3 million for 2010 compared to \$1.9 million for 2009. These special charges were primarily related to the relocation of our U.S. headquarters and the establishment of our sales office in the United Kingdom. Both of these activities began in the second quarter of 2009. The majority of the expenses related to these activities were recognized in 2009 and completed in the first quarter of 2010. These consolidation and restructuring activities were intended to result in a more efficient use of space and resources within our U.S. operations. The net impact on future periods is expected to be immaterial because the reduction in lease expense and headcount will be offset by additional lease costs in our remaining U.S. facilities to accommodate relocated employees as well as by increased headcount to perform activities within the remaining U.S. locations, including certain activities previously performed by terminated individuals.

Interest expense. Our interest expense increased by 10% to \$21.6 million in 2010 from \$19.7 million in 2009 due to the issuance of €37 million of 8% notes payable together with warrants to purchase 8.8 million ordinary shares in April of 2009. Interest expense for 2010 includes a full year of interest expense related to the 8% stated interest on the notes, together with additional interest expense related to the notes being issued at a discount as they were issued in conjunction with warrants. In February 2011, we repaid all of the outstanding indebtedness under our notes payable and at the time of repayment, we recognized a loss on debt extinguishment of approximately \$29.5 million

Table of Contents

and related deferred tax benefit of \$7.5 million to recognize the remaining balance of unamortized discount on the notes, and to reverse the related deferred tax liability.

Foreign currency transaction gain (loss). We recorded a foreign currency transaction loss of \$8.2 million in 2010 and a foreign currency transaction gain of \$3.0 million in 2009. The primary driver of our foreign currency transaction loss in 2010 and gain in 2009 is related to the revaluation of our warrant liability, which was denominated in a currency other than that of our parent legal entity. We recorded a foreign currency loss of \$11.6 million and gain of \$3.9 million in 2010 and 2009, respectively, to revalue the warrant liability. The offsetting foreign currency gains and losses in each period relate to the impact of revaluing certain of our intercompany debt and payables between our U.S. and European subsidiaries as a result of changes in the Euro to U.S. dollar exchange rate.

Other non-operating (expense) income. We recorded other non-operating income of less than \$0.1 million in 2010 and other non-operating loss of \$28.5 million in 2009. Our non-operating income and expense primarily relates to the adjustment of our warrant liability to fair value at the end of each reporting period. We settled our warrant liability in May of 2010 by exchanging all the outstanding warrants for our ordinary shares.

Income tax benefit. Our income tax benefit decreased \$9.3 million to \$5.1 million in 2010 compared to \$14.4 million in 2009. Our effective tax rate for 2010 and 2009 was 11% and 21%, respectively. Given our history of operating losses, we do not generally record a provision for income taxes in the United States and certain of our European sales offices. Our income tax benefit in both 2010 and 2009 primarily relate to tax benefit recorded related to our French subsidiaries and the reversal of deferred tax liabilities recognized in the Netherlands related to the debt discount on the notes payable issued in 2008 and 2009. Income tax benefit recognized in 2009 also included \$2.8 million related to a change in applicable law allowing for a one-time ability to carry back losses for five years in the United States.

Fiscal Year Ended December 27, 2009 Compared to Fiscal Year Ended December 28, 2008

Revenue. Revenue increased by 14% to \$201.5 million in 2009 from \$177.4 million in 2008, primarily as a result of growth in our target markets, new product launches and market share gains by our shoulder and ankle joint replacement products. During 2009, we launched 18 new products; six of these new products were introduced primarily in the United States. Our revenue was negatively impacted by approximately \$4.5 million during 2009 as a result of foreign currency fluctuations, principally due to the performance of the Euro against the U.S. dollar. Excluding the impact of the change in foreign currency exchange rates, our revenue increased by 16%.

Revenue by product category. Revenue in upper extremity joints and trauma product category increased by 15% to \$125.5 million in 2009 from \$108.8 million in 2008, primarily as a result of the continued increase in sales of our shoulder products, including our reversed shoulder and our Affiniti shoulder products, which launched at the end of 2008. We believe that increased sales of our reversed shoulder products resulted from continued market growth in shoulder replacement procedures and further market acceptance of our reversed and standard Aequalis shoulder joint replacement products. Our Affiniti shoulder products continued to grow in sales volume since their 2008 launch. Our upper extremity joints and trauma product category continues to represent the most significant group of products in our revenue, representing approximately 61% and 62% of revenue in 2008 and 2009, respectively. We expect our upper extremity joints and trauma product category will remain a significant portion of revenue in the immediate future and will be a primary driver of our anticipated 2010 revenue growth. Revenue in our lower extremity joints and trauma product category increased by 12% to \$20.4 million in 2009 from \$18.2 million in 2008, primarily due to high volume growth in our U.S. ankle products, which we believe was driven by our surgeon training and education efforts. Revenue in our sports medicine and biologics product category increased by 162% to \$6.6 million in

Table of Contents

2009 from \$2.5 million in 2008. This increase was attributable to the launch of our biologics product, Conexa, as well as increasing market acceptance of our Piton anchors. We expect revenue in this product category to increase as we focus on further developing and broadening these products. Revenue in the large joint and other product category increased by 2% to \$49.0 million in 2009 from \$47.9 million in 2008. Our large joint products are primarily sold internationally and were negatively impacted by the strengthening of the U.S. dollar. Excluding the impact of currency fluctuations, our large joint sales increased by 7%, driven primarily by an increase in sales volumes of certain of our hip products during 2009. We also launched the HLS Kneetec, a new knee joint implant, during 2009 to continue to strengthen our knee product revenue. We have made the strategic decision to focus the sale of our large joint products only in select international markets.

Revenue by geography. Revenue in the United States increased by 24% to \$112.6 million in 2009 from \$91.1 million in 2008. Revenue internationally increased by 3% to \$88.9 million in 2009 from \$86.3 million in 2008. Our international revenue was negatively impacted by approximately \$4.5 million during 2009 as a result of foreign currency fluctuations, principally due to the performance of the Euro against the U.S. dollar. Excluding the impact of the change in currency exchange rates, our international revenues increased by 8%, driven primarily by increased sales in our French market as well as in Germany and Australia.

Cost of goods sold. Our cost of goods sold increased by 21% to \$54.9 million in 2009 from \$45.5 million in 2008, primarily attributable to increased manufacturing overhead costs to support increased production capacity, which grew at a rate higher than production during 2008, the period in which the majority of our 2009 product sales were manufactured. As a percentage of revenue, cost of goods sold increased to 27% in 2009 from 26% in 2008, as we increased our manufacturing overhead costs in an effort to establish a sufficient level of capacity and manufacturing infrastructure to support our current and future growth plans. During 2009, we leased and moved into a new manufacturing facility in Macroom, Ireland, which should enable us to expand our Irish manufacturing capacity. We also purchased a new facility in Grenoble, France in 2009, which expanded our manufacturing facilities in France. Our increases in manufacturing overhead costs have grown at a rate faster than our factory output in recent years, causing an increase in the fully absorbed cost of our products. However, this has allowed us to establish an infrastructure that we believe will be able to sustain our sales growth plans and has increased our ability to leverage our costs in the future. In addition, we experienced charges for excess and obsolete inventory of \$6.8 million during 2009 compared to \$3.6 million during 2008 as a result of higher levels of obsolete inventory from a higher level of new product launches during 2009 and an increase in estimated shrinkage of U.S. consigned inventory. We also incurred certain one-time charges for relocating our Ireland manufacturing facility during 2009. Our cost of goods sold and corresponding gross profit as a percentage of revenue can be expected to fluctuate in future periods depending on changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses, levels of production volume and foreign currency exchange rates.

Selling and marketing. Our selling and marketing expenses increased by 8% to \$115.6 million in 2009 from \$106.9 million in 2008, primarily as a result of \$5.2 million of higher variable commissions and royalty expenses related to higher revenue, \$3.0 million of increased instrumentation depreciation and \$3.1 million of increased selling expenses related to new product promotions and training offset by a positive impact of \$2.6 million due to changes in foreign currency exchange rates. Selling and marketing expense as a percentage of revenue decreased from 60% in 2008 to 57% in 2009, primarily as a result of our ability to increase revenue at a higher rate than the increases in our existing sales and distribution expenses. We believe this reflects the results of our having increased sales and marketing expenses in prior years to build a sales and distribution infrastructure capable of supporting the revenue growth we experienced in 2009. While we believe our existing infrastructure is sufficient to

Table of Contents

support our 2010 growth plans, we do not anticipate that our selling and marketing expenses will decrease as a percentage of revenue during 2010.

General and administrative. Our general and administrative expenses decreased by 4% to \$20.8 million in 2009 from \$21.7 million in 2008, primarily as a result of the consolidation of certain administrative functions in France related to a subsidiary acquired in the Nexa acquisition, combined with a reduction of certain French property taxes. As a percentage of revenue, general and administrative expenses decreased two percentage points from 12% in 2008 to 10% in 2009. We were able to decrease our general and administrative expenses as a percentage of revenue during 2009 through controlled expenditures on certain legal and administrative costs; however, given our preparation for an initial public offering of our ordinary shares, we expect that general and administrative expense could increase and we may not be able to continue to decrease our general and administrative costs as a percentage of revenue in 2010.

Research and development. Research and development expenses decreased by 12% to \$18.1 million in 2009 from \$20.6 million in 2008, primarily due to favorable foreign currency exchange rates and consolidation of certain research and development activities into our Warsaw, Indiana facility. Research and development expenses represented 9% and 12% of revenue in 2009 and 2008, respectively. We believe that continued investment in research and development is an important part of sustaining our growth strategy through new product development and anticipate that research and development expenses as a percentage of revenue in 2010 will remain at a level similar to 2009.

Amortization of intangible assets. Amortization of intangible assets increased by 36% to \$15.2 million in 2009 from \$11.2 million in 2008 primarily as a result of \$3.4 million of impairment charges recorded in 2009 from the abandonment of certain previously acquired developed technology and a full year of amortization related to the intangible asset recorded upon the consolidation of C2M Medical in 2008.

Special charges. In 2009, we recorded special charges totaling \$1.9 million related to the consolidation and restructuring of certain activities in our Boston, New Jersey and San Diego facilities, as well as the relocation of our U.S. headquarters. These consolidation and restructuring activities were intended to result in a more efficient use of space and resources within our U.S. operations. The net impact on future periods is expected to be immaterial because the reduction in lease expense and headcount will be offset by additional lease costs in our remaining U.S. facilities to accommodate relocated employees as well as by increased headcount to perform activities within the remaining U.S. locations, including certain activities previously performed by terminated individuals.

Interest expense. Our interest expense increased by 76% to \$19.7 million in 2009 from \$11.2 million in 2008 due to the full year impact of interest related to €34.5 million of notes payable issued in February 2008 and €37.0 million of notes payable issued in April 2009. Of the \$19.7 million of interest expense in 2009, \$10.0 million relates to non-cash amortization of debt discount recorded on the notes payable issued in both 2008 and 2009 and \$7.3 million relates to paid-in-kind interest accrued as additional principal value of the notes payable issued in 2008 and 2009.

Foreign currency transaction gain (loss). Our foreign currency transaction gain increased by 77% to \$3.0 million in 2009 from \$1.7 million in 2008. During 2009, we recorded a \$3.9 million foreign currency gain related to the revaluation of our warrant liability, which is denominated in a currency other than our functional currency. The remaining foreign currency gains in 2009 and 2008 relate primarily to the impact of revaluing certain of our intercompany debt and payables between our U.S. and European subsidiaries as a result of changes in the Euro to U.S. dollar exchange rate.

Table of Contents

Other non-operating (expense) income. Other non-operating expenses increased to \$28.5 million in 2009 from \$1.4 million in 2008 due to the charge recorded as a result of the change in the fair value of the warrant liability issued with the 2008 and 2009 notes payable. This increase in fair value primarily relates to our change in the estimated fair value of our ordinary shares from \$16.98 per share at the end of 2008 to \$22.50 per share at the end of 2009.

Income tax benefit. Our income tax benefit increased \$9.2 million to \$14.4 million in 2009 compared to \$5.2 million in 2008. Our effective tax rate for 2009 and 2008 was 21% and 13%, respectively. Given our history of operating losses, we do not generally record a provision for income taxes in the United States and certain of our European sales offices. During 2009, we recorded a \$3.2 million tax benefit related to losses incurred in France that we believe will be realizable in the future because of the existence of sufficient deferred tax liabilities that will reverse over time, creating future taxable income. We also recorded a \$2.8 million income tax benefit in the United States as a result of a law change allowing for a one-time ability to carry back our current year losses for five years. Finally, we recorded a \$9.2 million income tax benefit related to the reversal of deferred tax liabilities on the debt discount recorded on the notes payable issued in 2008 and 2009.

Seasonality and Quarterly Fluctuations

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; 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; increased competition; the timing and extent of promotional pricing or volume discounts; changes in average selling prices; the availability and cost of components and materials; number of selling days; fluctuations in foreign currency exchange rates; and impairment and other special charges. In addition, we issued notes payable and warrants in both 2008 and 2009 in order to raise working capital. During 2009, we adopted new accounting guidance that requires we record the fair value of the warrants as a liability on our balance sheet and adjust that liability to fair value at each reporting period, changes in which are recognized as either an expense or gain in our statement of operations.

Liquidity and Capital Resources

Since inception, we have generated significant operating losses. These, combined with significant charges not related to cash from operations, amortization of acquired intangible assets, fair value adjustments to our warrant liability and accretion of noncontrolling interests, have resulted in an accumulated deficit of \$183.5 million as of January 2, 2011. Historically, our liquidity needs have been met through a combination of sales of our equity securities together with issuances of notes payable and warrants to both current shareholders and new investors and other bank related debt. Our notes payable have financial and operational covenants that could limit our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. As of January 2, 2011, we have \$53.9 million in short-term and long-term debt excluding our notes payable. Certain of these other debt agreements also include financial covenants that (i) require us to have a minimum level of tangible net worth in our U.S. operating subsidiary, (ii) have various levels of performance tests of debt to equity and debt to modified income specifically related to our French operating subsidiary and (iii) restrict our ability to borrow in our U.S. operating subsidiary if there is a default under the agreement, all of which may have an impact on our liquidity.

Table of Contents

The following table sets forth, for the periods indicated, certain liquidity measures:

	January 2, 2011	As of December 27, 2009	December 28, 2008
	(\$ in thousands)		
Cash and cash equivalents	\$ 24,838	\$ 37,969	\$ 21,348
Working capital	96,965	98,993	66,779
Line of credit availability	11,252	13,530	7,927

Operating activities. Net cash provided by operating activities was \$2.9 million in 2010 compared to net cash provided by operating activities of \$2.3 million in 2009. The increase was primarily driven by an improvement in our consolidated net loss adjusted for non-cash items and a decrease in accounts payable offset by increases in inventory and receivables. Net cash provided by operating activities was \$2.3 million in 2009 compared to net cash used in operating activities of \$19.5 million in 2008. This improvement in our cash flows from operations was primarily driven by an improvement in our consolidated net loss adjusted for non-cash items by approximately \$17.1 million, due to our increased leverage on operating expenses versus our increase in revenue. In addition, we decreased inventory by \$4.3 million due to improved inventory management and lower levels of inventory to support product launches. We also experienced \$5.4 million in favorable cash flows from lower receivable balances as a result of improved collection efforts in 2009. These cash flow improvements were partially offset by other changes in current assets and liabilities.

Investing activities. Net cash used in investing activities totaled \$22.9 million, \$31.1 million and \$43.3 million in 2010, 2009 and 2008, respectively. Amounts related to the addition of surgical instrumentation equipment were \$13.8 million, \$12.3 million and \$18.2 million in 2010, 2009 and 2008, respectively. The investments in surgical instrumentation in 2010 and 2009 relate primarily to supporting continued revenue growth as well as certain new product launches. Investment in surgical instrumentation was higher in 2008 than 2009 due to increased building of instrument sets in 2008 to support product launches in subsequent years. Amounts related to property, plant and equipment were \$6.7 million, \$11.1 million and \$13.5 million in 2010, 2009 and 2008, respectively. Property, plant and equipment additions in 2010 primarily related to preparing our new France manufacturing facility to begin production. In 2009 we used approximately \$2.4 million on leasehold improvements in conjunction with moving our Irish manufacturing operations into a newly leased facility. In 2008, we used approximately \$6.1 million to purchase a new manufacturing facility in Grenoble, France. Acquisition-and licensing-related payments totaled \$2.3 million, \$7.7 million and \$12.7 million in 2010, 2009 and 2008, respectively. Acquisition and licensing related payments in 2010 were related to contingent purchase price from a previous acquisition, as certain milestones were achieved in the first two quarters of 2010 and continued payments of contingent purchase price related to our consolidated subsidiary's acquisition of our Piton technology. The purchase agreement related to our acquisition of our Piton technology requires that we make payments equal to 25% of the sales of Piton for a three-year period ending in the fourth quarter of 2011. Acquisition and licensing related payments in 2009 were related to earn-out payments made to the shareholders of DVO as a part of the asset purchase agreement we entered into in 2007. These were the final earn-out payments to be made under this agreement.

Our industry is capital intensive, particularly as it relates to surgical instrumentation. Historically, our capital expenditures have consisted principally of purchased manufacturing equipment, research and testing equipment, computer systems, office furniture and equipment and surgical instruments.

Financing activities. Net cash provided by financing activities totaled \$7.4 million, \$44.9 million and \$66.5 million in 2010, 2009 and 2008. During 2010, we used \$3.5 million for deferred financing costs related to our initial public offering completed in 2011. During 2010, we also generated

Table of Contents

\$6.5 million from the increase in short-term debt and \$3.7 million from new long-term borrowing arrangements net of payments on long-term debt. This compares to payments of \$3.5 million on short-term debt and payments made of \$3.9 million on long-term borrowing arrangements, net of cash generated from new long-term borrowing arrangements during 2009. The increase in proceeds generated by the issuance of long-term debt was due to our ability to raise a higher level of term loans in France secured by certain working capital balances during 2010. During 2009 and 2008, proceeds of \$49.3 million and \$52.4 million, respectively, were generated from the issuance of notes payable and warrants to be used as working capital. Proceeds of \$2.9 million and \$8.9 million were generated in 2009 and 2008, respectively, through the sale of our ordinary shares to various investors.

Other liquidity information. We have funded our cash needs since our acquisition in 2006 through the issuance of equity, notes payable and warrants to a group of investors. In February of 2011, we completed an initial public offering and raised net proceeds of \$155.4 million. Although it is difficult for us to predict our future liquidity requirements, we believe that our current cash balance of approximately \$24.8 million, the additional cash raised in our 2011 initial public offering and our existing available credit lines of \$11.3 million will be sufficient to fund our working capital requirements and operations and permit anticipated capital expenditures in 2011. Our European subsidiaries have established a combination of secured and unsecured available lines of credit totaling \$21.9 million as of January 2, 2011. The secured lines of credit generally have between one and two year terms and are renewed at the end of the related term. The unsecured lines of credit do not include specific terms and can be terminated by the banks upon 60 days notice. These lines of credit have variable interest rates based on the Euro Overnight Index Average plus 1.3% or a three-month Euro rate plus 0.5%-3.0%. We also have a \$10.0 million credit line secured by our U.S. operating subsidiary which was renewed in August 2010. This line is secured by working capital and equipment and bears interest at a 30-day LIBOR plus 2.25% interest rate. 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. 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. There is no assurance that any financing transaction will be available on terms acceptable to us, or at all.

Contractual Obligations and Commitments

The following table summarizes our outstanding contractual obligations as of January 2, 2011 for the categories set forth below, assuming only scheduled amortizations and repayment at maturity:

	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
(\$ in thousands)					
<i>Amounts reflected in consolidated balance sheet:</i>					
Bank debt	\$ 50,356	\$ 28,076	\$ 11,915	\$ 6,115	\$ 4,250
Notes payable	95,538		95,538		
Shareholder loan	2,356				2,356
Capital leases	1,148	316	665	167	
<i>Amounts not reflected in consolidated balance sheet:</i>					
Interest on bank debt	3,782	1,886	1,290	606	
Accrued paid-in-kind interest on notes payable	45,962		45,962		
Interest on capital leases	161	81	74	6	
Operating leases	17,523	4,691	5,138	3,572	4,122
Total	\$ 216,826	\$ 35,050	\$ 160,582	\$ 10,466	\$ 10,728

Table of Contents

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC, that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

Critical Accounting Policies

Our consolidated financial statements and related financial information are based on the application of U.S. GAAP. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes.

Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our physician customers and information available from other outside sources, as appropriate. Changes in accounting estimates are reasonably likely to occur from period to period. Changes in these estimates and changes in our business could have a material impact on consolidated financial statements.

We believe that the following accounting policies are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recognized in our consolidated financial statements for all periods presented. Management has discussed the development, selection and disclosure of our critical financial estimates with the audit committee and our board of directors. The judgments about those financial estimates are based on information available as of the date of our consolidated financial statements. Our critical financial policies and estimates are described below:

Revenue Recognition

We derive our revenue from the sale of medical devices that are used by orthopaedic surgeons who treat diseases and disorders of extremity joints including the shoulder, elbow, wrist, hand, ankle and foot. Our revenue is generated from sales to two types of customers: healthcare institutions and distributors. Sales to healthcare institutions represent the majority of our revenue. We utilize a network of independent commission-based sales agencies for sales in the United States and a combination of direct sales organizations, independent sales representatives and distributors for sales outside the United States. Generally, revenue from sales to healthcare institutions is recognized at the time of surgical implantation. We generally record revenue from sales to our distributors at the time the product is shipped to the distributor. Distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at time of shipment. We do not have any arrangements with distributors that allow for retroactive pricing adjustments. Our distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. In certain circumstances, we may accept sales returns from distributors and in certain situations in which the right of return exists, we estimate a reserve for sales returns and recognize the reserve as a reduction of revenue. We base our estimate for sales returns on historical sales and product return information including historical experience and trend information. Our reserve for sales returns has historically been immaterial. We charge our customers for shipping and handling and recognize these amounts as part of revenue.

Table of Contents

Allowance for Doubtful Accounts

We maintain an allowance for doubtful accounts for estimated losses in the collection of accounts receivable. We make estimates regarding the future ability of our customers to make required payments based on historical credit experience, delinquency and expected future trends. The majority of our receivables are due from healthcare institutions, many of which are government funded. Accordingly, our collection history with this class of customer has been favorable and has resulted in a low level of historical write-offs. We write off accounts receivable when we determine that the accounts receivable are uncollectible, typically upon customer bankruptcy or the customer's non-response to continued collection efforts.

We believe that the amount included in our allowance for doubtful accounts has been a historically appropriate estimate of the amount of accounts receivable that is ultimately not collected. While we believe that our allowance for doubtful accounts is adequate, the financial condition of our customers and the geopolitical factors that impact reimbursement under individual countries' healthcare systems can change rapidly, which may necessitate additional allowances in future periods. Our allowance for doubtful accounts was \$2.5 million and \$2.7 million at January 2, 2011 and December 27, 2009, respectively.

Excess and Obsolete Inventory

We value our inventory at the lower of the actual cost to purchase or manufacture the inventory on a first-in, first-out, or FIFO, basis or its net realizable value. We regularly review inventory quantities on hand for excess and obsolete inventory and, when circumstances indicate, we incur charges to write down inventories to their net realizable value. Our review of inventory for excess and obsolete quantities is based on an analysis of historical product sales together with our forecast of product demand and production requirements. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. Additionally, our industry is characterized by regular new product development that could result in an increase in the amount of obsolete inventory quantities on hand due to cannibalization of existing products. Also, our estimates of future product demand may prove to be inaccurate, in which case we may be required to incur charges for excess and obsolete inventory. In the future, if additional inventory write-downs are required, we would recognize additional cost of goods sold at the time of such determination. Regardless of changes in our estimates of future product demand, we do not increase the value of our inventory above its adjusted cost basis. Therefore, although we make every effort to ensure the accuracy of our forecasts of future product demand, significant unanticipated decreases in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results. Charges incurred for excess and obsolete inventory were \$5.2 million, \$6.8 million and \$3.6 million for the fiscal years ended 2010, 2009 and 2008, respectively.

Instruments

Instruments are surgical tools used by orthopaedic surgeons during joint replacement and other surgical procedures to facilitate the implantation of our products. There are no contractual terms with respect to the usage of our instruments by our customers. Surgeons are under no contractual commitment to use our instruments. We maintain ownership of these instruments and, when requested, we allow the surgeons to use the instruments to facilitate implantation of our related products. We do not currently charge for the use of our instruments and there are no minimum purchase commitments relating to our products. As our surgical instrumentation is used numerous times over several years, often by many different customers, instruments are recognized as long-lived assets once they have been placed in service. Instruments, and instrument parts, that have not been placed in service are carried at cost, net of allowances for excess and obsolete instruments, and are included as instruments in progress within instruments, net on the consolidated balance sheets. Once placed in service, instruments are

Table of Contents

carried at cost, less accumulated depreciation. Depreciation is computed using the straight-line method based on average estimated useful lives. Estimated useful lives are determined principally in reference to associated product life cycles, and average five years. As instruments are used as tools to assist surgeons, depreciation of instruments is recognized as a sales and marketing expense. Instrument depreciation expense was \$9.4 million, \$9.4 million and \$6.3 million during 2010, 2009 and 2008, respectively.

We review instruments for impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the assets are less than the asset's carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value.

Goodwill and Long-Lived Assets

We have approximately \$131.8 million of goodwill recorded as a result of the acquisition of businesses. Goodwill is tested for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest that impairment exists. Based on our single business approach to decision-making, planning and resource allocation, we have determined that we have one reporting unit for purposes of evaluating goodwill for impairment. We use widely accepted valuation techniques to determine the fair value of our reporting unit used in our annual goodwill impairment analysis. Our valuation is primarily based on the income approach that is supported by a discounted cash flow analysis. The market approach used consists of comparisons to the valuations of a group of guideline public companies. We do not currently generate earnings from operations and therefore do not use the results of the market approach in our valuation. Rather, the results of our market approach are used to evaluate the reasonableness of the income approach. We performed our annual impairment test on the first day of the fourth quarter of 2010 and determined that the fair value of our reporting unit exceeded its carrying value and, therefore, no impairment charge was necessary.

The impairment evaluation related to goodwill requires the use of considerable management judgment to determine discounted future cash flows, including estimates and assumptions regarding the amount and timing of cash flows, cost of capital and growth rates. Cash flow assumptions used in the assessment are estimated using assumptions in our annual operating plan as well as our five-year strategic plan. Our annual operating plan and strategic plan contain revenue assumptions that are derived from existing technology as well as future revenues attributed to in-process technologies and the associated launch, growth and decline assumptions normal for the life cycle of those technologies. In addition, management considers relevant market information, peer company data and historical financial information. We also considered our historical operating losses in assessing the risk related to our future cash flow estimates and attempted to reflect that risk in the development of our weighted average cost of capital.

We depreciate our property, plant and equipment and amortize our intangible assets based upon our estimate of the respective asset's useful life. Our estimate of the useful life of an asset requires us to make judgments about future events, such as product life cycles, new product development, product cannibalization and technological obsolescence, as well as other competitive factors beyond our control. We account for the impairment of long-lived assets in accordance with FASB ASC Section 360, Property, Plant and Equipment (FASB ASC 360). Accordingly, when indicators of impairment exist, we evaluate impairments of our property, plant and equipment based upon an analysis of estimated undiscounted future cash flows. If we determine that a change is required in the useful life of an asset, future depreciation and amortization is adjusted accordingly. Alternatively, if we determine that an asset has been impaired, an adjustment would be charged to earnings based on the asset's fair market value, or discounted cash flows if the fair market value is not readily determinable, reducing revenue in that period.

Table of Contents

Warrant Liability

During 2009 and 2008 we raised additional working capital funds through the sale of notes payable and warrants to purchase our ordinary shares. In accordance with U.S. GAAP, these warrants were classified as a liability and carried at fair value because the warrants were denominated in a currency other than the functional currency of the issuing entity. We estimated the fair value of the warrant liability using a Black-Scholes option pricing model. The determination of the fair value of our warrant liability utilizing the Black-Scholes model is affected by our share price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life of our warrants was determined to be equal to the remaining contractual term as the warrants were fully detachable from the notes payable with which they were issued. As a non-public entity, historic volatility was not previously available for our ordinary shares. As a result, we estimated volatility based on a peer group of companies, which collectively provides a reasonable basis for estimating volatility. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term approximately equal to the remaining term of the warrants. The final input, which has a significant impact on the estimated fair value of our warrant liability, is our estimated fair value of our underlying ordinary shares. Refer to "Significant Factors Used in Determining Fair Value of Our Ordinary Shares" below for a detailed discussion of how we estimate the fair value of our underlying shares.

Accounting for Income Taxes

Our effective tax rate is based on income by tax jurisdiction, statutory rates and tax-saving initiatives available to us in the various jurisdictions in which we operate. Significant judgment is required in determining our effective tax rate and evaluating our tax positions. This process includes assessing temporary differences resulting from differing recognition of items for income tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. Realization of deferred tax assets in each taxable jurisdiction is dependent on our ability to generate future taxable income sufficient to realize the benefits. Management evaluates deferred tax assets on an ongoing basis and provides valuation allowances to reduce net deferred tax assets to the amount that is more likely than not to be realized.

Our valuation allowance balances totaled \$27.0 million and \$22.8 million as of January 2, 2011 and December 27, 2009, respectively, due to uncertainties related to our ability to realize, before expiration, some of our deferred tax assets for both U.S. and foreign income tax purposes. These deferred tax assets primarily consist of the carryforward of certain tax basis net operating losses and general business tax credits.

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), effective January 1, 2007, which requires the tax effects of an income tax position to be recognized only if they are more-likely-than-not to be sustained based solely on the technical merits as of the reporting date. On December 30, 2008, the FASB further delayed the effective date of this guidance for certain non-public enterprises until annual financial statements for fiscal years beginning after December 15, 2008. Effective July 1, 2009, this standard was incorporated into FASB ASC Section 740, Income Taxes. We adopted these provisions of ASC Section 740 in 2009. As a multinational corporation, we are subject to taxation in many jurisdictions and the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various taxing jurisdictions. If we ultimately determine that the payment of these liabilities will be unnecessary, we will reverse the liability and recognize a tax benefit in the period in which we determine the liability no longer applies. Conversely, we record additional tax charges in a period in which we determine that a recorded tax liability is less than we expect the ultimate assessment to be. Our liability for unrecognized tax benefits totaled \$2.1 million as of January 2, 2011.

Table of Contents**Share-Based Compensation**

The estimated fair value of share-based awards exchanged for employee and non-employee director services are expensed over the requisite service period. Option awards issued to non-employees (excluding non-employee directors) are recorded at their fair value as determined in accordance with authoritative guidance, are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating share-based compensation, we estimate the fair value of stock options using a Black-Scholes option pricing model. The determination of the fair value of share-based payment awards utilizing this Black-Scholes model is affected by our share price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends.

We do not have information available which is indicative of future exercise and post-vesting behavior to estimate the expected term. As a result, we adopted the simplified method of estimating the expected term of a stock option, as permitted by the Staff Accounting Bulletin No. 107. Under this method, the expected term is presumed to be the mid-point between the vesting date and the contractual end of the term. As a non-public entity prior to February 2011, historic volatility was not available for our ordinary shares. As a result, we estimated volatility based on a peer group of companies, that we believe collectively provides a reasonable basis for estimating volatility. We intend to continue to consistently use the same group of publicly traded peer companies to determine volatility in the future until sufficient information regarding volatility of our ordinary share price becomes available or the selected companies are no longer suitable for this purpose. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term approximately equal to the expected life of our stock options. The estimated pre-vesting forfeiture rate is based on our historical experience together with estimates of future employee turnover. We do not expect to declare dividends in the foreseeable future.

The following table summarizes the amount of share-based compensation expense recognized in our statements of operations by expense category:

	January 2, 2011	Year ended December 27, 2009	December 28, 2008
	(\$ in thousands)		
Cost of goods sold	\$ 536	\$ 77	\$ 341
Selling and marketing	1,800	1,306	1,034
General and administrative	2,861	2,250	2,051
Research and development	433	280	246
Total share-based compensation	\$ 5,630	\$ 3,913	\$ 3,672

If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining share-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining share-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. We expect to continue to grant stock options in the future, and to the extent that we do, our actual share-based compensation expense recognized in future periods will likely increase.

Significant Factors Used in Determining Fair Value of Our Ordinary Shares

The fair value of our ordinary shares that underlie the stock options we have granted has historically been determined by our board of directors based upon information available to it at the

Table of Contents

time of grant. Because, prior to our initial public offering, there has been no public market for our ordinary shares, our board of directors has determined the fair value of our ordinary shares by utilizing, among other things, transactions involving sales of our ordinary shares, other financing events involving our ordinary shares and contemporaneous valuation studies conducted as of January 31, 2008, and December 27, 2009. The findings of these valuation studies were based on our business and general economic, market and other conditions that could be reasonably evaluated at that time. The analyses of the valuation studies incorporated extensive due diligence that included a review of our company, including its financial results, business agreements, intellectual property and capital structure. The valuation studies also included a thorough review of the conditions of the industry in which we operate and the markets that we serve. The methodologies of the valuation studies included an analysis of the fair market value of our company using three widely accepted valuation methodologies: (1) market multiple, (2) comparable transactions and (3) discounted cash flow. These valuation methodologies were based on a number of assumptions, including our forecasted future revenue and industry, general economic, market and other conditions that could reasonably be evaluated at the time of the valuation.

The market multiple methodology involved the multiplication of revenue by risk-adjusted multiples. Multiples were determined through an analysis of certain publicly traded companies, which were selected on the basis of operational and economic similarity with our principal business operations. Revenue multiples, when applicable, were calculated for the comparable companies based upon daily trading prices. A comparative risk analysis between us and the public companies formed the basis for the selection of appropriate risk-adjusted multiples for our company. The risk analysis incorporated factors that relate to, among other things, the nature of the industry in which we and other comparable companies are engaged. The comparable transaction methodology also involved multiples of earnings and cash flow. Multiples used in this approach were determined through an analysis of transactions involving controlling interests in companies with operations similar to our principal business operations. The discounted cash flow methodology involved estimating the present value of the projected cash flows to be generated from the business and theoretically available to the capital providers of our company. A discount rate was applied to the projected future cash flows to reflect all risks of ownership and the associated risks of realizing the stream of projected cash flows. Since the cash flows were projected over a limited number of years, a terminal value was computed as of the end of the last period of projected cash flows. The terminal value was an estimate of the value of the enterprise on a going concern basis as of that future point in time. Discounting each of the projected future cash flows and the terminal value back to the present and summing the results yielded an indication of value for the enterprise. Our board of directors took these three approaches into consideration when establishing the fair value of our ordinary shares.

The fair value of our ordinary shares was initially established on July 18, 2006, based on the price per share paid in the Investor Group's initial acquisition. During the first quarter of 2007, we sold approximately \$92.6 million of additional ordinary shares to our existing shareholders at a price of \$13.89 per share to fund certain acquisitions. This price was then used as the fair value of our ordinary shares until December 31, 2007. During 2007, we began to integrate three acquired companies, all of which expanded our product portfolio and helped to increase our sales by 22%. On January 1, 2008, we increased the value of our ordinary shares to \$16.98 per share based on the conclusions of our board of directors in analyzing several factors including an independent valuation. We believe this increase in fair value was warranted based on several factors including our continued revenue growth and broadening product portfolio, offset by our increased operating expenses from the acquired business. From January 1, 2008 to December 27, 2009, we granted 1,105,416 stock options at an exercise price of \$16.98 per share. During this period, we continued to experience revenue growth through continued product launches, new product licensing transactions and increased volumes and market share. However, during the same period we increased manufacturing costs and operating expenses to build an operational foundation on which we could sustain continued double digit revenue growth. As a result, we experienced a decrease in our operating profitability and higher levels of cash used to sustain our

Table of Contents

operations compared to 2007. As a result of our continued high growth offset by increased spending levels, we determined that a change in the fair value of our ordinary shares was not necessary. This determination was supported by the fact that, during this time, we sold additional shares of our ordinary shares to various investors, including former shareholders of one of our 2007 acquisitions and certain other business partners, all at a price of \$16.98 per share. During this time, we also raised additional working capital through the sale of \$52.4 million of notes payable and warrants in February 2008 and \$49.3 million of notes payable and warrants in April 2009. These sales of notes payable and warrants were to a combination of then current investors, certain new investors and members of management. In both instances, the exercise price of the warrants sold was set at \$16.98 per share as we continued to estimate the value of our ordinary shares to be \$16.98 per share. On December 27, 2009, we decided to increase our estimate of the fair value of our ordinary shares to \$22.50 per share. Our estimated fair value of \$22.50 per share was determined by our board of directors based on several factors including an independent valuation discussed previously. We believed the increase in the estimated fair value of our ordinary shares was appropriate during 2009 as our sales continued to grow at a high rate while our operating profit, excluding depreciation, amortization and share-based compensation, began to increase and our cash flow from operations also improved substantially. Stock options granted during these periods had exercise prices equal to the then estimated fair value of our ordinary shares.

We also granted 765,464 options in June of 2010 as part of our annual option grants as well as for certain new employees and a new director. These options were granted within an exercise price of \$22.50 per share which we estimated to be the fair value of our underlying shares at the dates of grant. Our board of directors estimated the fair value of our underlying ordinary shares during 2010 by reviewing various factors including our first quarter results, current market conditions, the impact of various 2010 corporate transactions and by reviewing an updated independent valuation report. We believed that certain factors were increasing the fair value of our ordinary shares such as a shortened time period between the estimated valuation date and the estimated date of our pending initial public offering which would reduce the discount to our ordinary shares for the current lack of liquidity and marketability. However, this increase in fair value was offset by two dilutive transactions occurring in 2010 in which we issued additional ordinary shares in our acquisition of C2M and in the exchange of all previously outstanding warrants for ordinary shares (refer to Note 14 of the consolidated financial statements). Both of these transactions included the issuance of additional ordinary shares without corresponding increases in our overall estimated enterprise value. As a result, these transactions reduced the fair value of our ordinary shares on a per share basis. As a result of our analyses, we determined that the fair value of our ordinary shares was \$22.50 per ordinary share. The weighted average fair value of the option grants was \$11.07 per share aggregating total future compensation of \$8.5 million, reduced by our ongoing estimates of expected forfeitures, to be recognized over the four year period subsequent to the respective dates of grant.

In October 2010 and December 2010 we granted 135,333 and 95,833 options, respectively, to certain employees. The options were granted with an exercise price of \$22.50 per share, which we estimated to be the fair value of our underlying ordinary shares at each grant date.

Recent Accounting Pronouncements

In December 2009, the FASB issued Accounting Standards Update (ASU) 2009-17, *Consolidations (ASC Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*. ASU 2009-17 requires a qualitative approach to identifying a controlling financial interest in a variable interest entity (VIE), and requires ongoing assessment of whether an entity is a VIE and whether an interest in a VIE makes the holder the primary beneficiary of the VIE. The adoption of ASU 2009-17 in January 2010 did not have a material impact on the Company's consolidated financial statements.

Table of Contents

In January 2010, the FASB issued ASU 2010-6, *Fair Value Measurements and Disclosures (ASC Topic 820): Improving Disclosures about Fair Value Measurements*, which requires reporting entities to make new disclosures about recurring or nonrecurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU2010-6 was effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for interim and annual periods beginning after December 15, 2010. The Company adopted the additional disclosures required for Level 1 and Level 2 fair value measurements in the first quarter of 2010. The Company will adopt Level 3 disclosures beginning in the first quarter of 2011.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign currency exchange rate fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes. We believe we are not exposed to a material market risk with respect to our invested cash and cash equivalents.

Interest Rate Risk

Borrowings under our various revolving lines of credit in the United States and in Europe generally bear interest at variable annual rates. Borrowings under our various term loans in the United States and Europe are mixed between variable and fixed interest rates. As of January 2, 2011, we had \$20.6 million in borrowings under our revolving lines of credit and \$33.2 million in borrowings under various term loans. Based upon this debt level, a 10% increase in the interest rate on such borrowings would not have a material impact on interest expense.

At January 2, 2011, our cash and cash equivalents were \$24.8 million. Based on our annualized average interest rate, a 10% decrease in the interest rate on such balances would not have a material impact on interest expense.

Foreign Currency Exchange Rate Risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. In fiscal years 2010, 2009 and 2008, approximately 44%, 44% and 49%, respectively, of our sales were denominated in foreign currencies. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Operating expenses related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not significant. However, for sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases and if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our prices not being competitive in a market where business is transacted in the local currency.

In 2010, approximately 83% of our foreign currency denominated sales were derived from EU countries and were denominated in Euros. Additionally, we have significant intercompany payables and debt with certain European subsidiaries, which are denominated in foreign currencies, principally the Euro. Our principal exchange rate risk therefore exists between the U.S. dollar and the Euro.

Table of Contents

Fluctuations from the beginning to the end of any given reporting period result in the remeasurement of our foreign currency-denominated cash, receivables, payables and debt-generating currency transaction gains or losses that impact our non-operating revenue/expense levels in the respective period and are reported in foreign currency transaction gain (loss) in our consolidated financial statements. We recorded a foreign currency transaction loss of approximately \$8.2 million in 2010 related to the translation of our foreign-denominated receivables, payables and debt into U.S. dollars. We do not currently hedge our exposure to foreign currency exchange rate fluctuations. We may, however, hedge such exposure to foreign currency exchange rates in the future.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

<u>Report of Independent Registered Public Accounting Firm</u>	<u>83</u>
<u>Consolidated Balance Sheets</u>	<u>84</u>
<u>Consolidated Statements of Operations</u>	<u>85</u>
<u>Consolidated Statements of Cash Flows</u>	<u>86</u>
<u>Consolidated Statements of Shareholders' Equity and Comprehensive Loss</u>	<u>87</u>
<u>Notes to Consolidated Financial Statements</u>	<u>88</u>
	82

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors
Tornier B.V.

We have audited the accompanying consolidated balance sheets of Tornier B.V. and subsidiaries (the Company) as of January 2, 2011 and December 27, 2009, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended January 2, 2011. Our audits also included the financial statement schedule listed in Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Tornier B.V. and subsidiaries at January 2, 2011 and December 27, 2009, and the consolidated results of their operations and their cash flows for each of the three fiscal years in the period ended January 2, 2011, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 2 of the consolidated financial statements, the Company adopted the provisions of ASC Topic 740, *Income Taxes*, related to accounting for uncertainty in income taxes, as of December 29, 2008. Additionally, as discussed in Note 7 of the consolidated financial statements, the Company adopted the provisions of ASC Topic 815-40, *Derivatives and Hedging*, and changed its method of accounting for certain instruments indexed to the Company's own stock.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
March 11, 2011

Table of Contents**Tornier B.V.****Consolidated Balance Sheets****(in thousands except per share data)**

	January 2, 2011	December 27, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,838	\$ 37,969
Accounts receivable (net of allowance of \$2,519 and \$2,667, respectively)	42,758	40,447
Inventories	77,525	68,621
Income taxes receivable	2,835	2,835
Deferred income taxes	2,587	2,860
Prepaid taxes	11,179	10,356
Prepaid expenses	7,444	3,353
Other current assets	4,048	4,707
Total current assets	173,214	171,148
Instruments, net	42,378	40,450
Property, plant, and equipment, net	33,680	35,076
Goodwill	131,830	136,949
Intangible assets, net	109,024	125,221
Deferred income taxes	440	10,530
Other assets	612	813
Total assets	\$ 491,178	\$ 520,187
Liabilities and shareholders' equity		
Current liabilities:		
Short-term borrowing and current portion of long-term debt	\$ 28,392	\$ 23,299
Accounts payable	12,890	12,925
Accrued liabilities	34,620	35,580
Income taxes payable	327	351
Deferred income taxes	20	
Total current liabilities	76,249	72,155
Notes payable	84,261	69,535
Other long-term debt	25,467	22,889
Deferred income taxes	28,706	21,557
Warrant liabilities		85,215
Contingent liabilities	1,860	3,167
Other non-current liabilities	4,396	2,622
Total liabilities	220,939	277,140
Redeemable non-controlling interest		23,259
Shareholders' equity:		
Ordinary shares, \$0.03 par value; authorized 100,000,000; issued and outstanding 29,568,731 and 24,666,970 at January 2, 2011 and December 27, 2009, respectively	1,156	968
Additional paid-in capital	437,307	344,049
Accumulated deficit	(183,532)	(144,718)
Accumulated other comprehensive income	15,308	19,489

Edgar Filing: Tornier N.V. - Form 10-K

Total shareholders' equity	270,239	219,788
Total liabilities and shareholders' equity	\$ 491,178	\$ 520,187

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**Tornier B.V.****Consolidated Statements of Operations****(in thousands except per share data)**

	January 2, 2011	Fiscal Year Ended December 27, 2009	December 28, 2008
Revenue	\$ 227,378	\$ 201,462	\$ 177,370
Cost of goods sold	63,437	54,859	45,500
Gross profit	163,941	146,603	131,870
Operating expenses:			
Sales and marketing	126,809	115,630	106,870
General and administrative	22,366	20,790	21,742
Research and development	17,896	18,120	20,635
Amortization of intangible assets	11,492	15,173	11,186
Special charges	306	1,864	
Total operating expenses	178,869	171,577	160,433
Operating loss	(14,928)	(24,974)	(28,563)
Other income (expense):			
Interest (expense)	(21,582)	(19,667)	(11,171)
Foreign currency transaction gain (loss)	(8,163)	3,003	1,701
Other non-operating income (expense), net	43	(28,461)	(1,371)
Loss before income taxes	(44,630)	(70,099)	(39,404)
Income tax benefit	5,121	14,413	5,227
Consolidated net loss	(39,509)	(55,686)	(34,177)
Net loss attributable to non-controlling interest	(695)	(1,067)	(1,173)
Net loss attributable to Tornier	(38,814)	(54,619)	(33,004)
Accretion of non-controlling interest	(679)	(1,127)	(3,761)
Net loss attributable to ordinary shareholders	\$ (39,493)	\$ (55,746)	\$ (36,765)
Net loss per share:			
Basic and diluted	\$ (1.42)	\$ (2.28)	\$ (1.54)
Weighted-average shares outstanding:			
Basic and diluted	27,770	24,408	23,930

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**Tornier B.V.****Consolidated Statements of Cash Flows****(in thousands)**

	January 2, 2011	Fiscal Year Ended December 27, 2009	December 28, 2008
Cash flows from operating activities:			
Consolidated net loss	\$ (39,509)	\$ (55,686)	\$ (34,177)
Adjustments to reconcile consolidated net loss to cash provided by (used in) operating activities:			
Depreciation and amortization	27,038	29,732	22,331
Non-cash foreign currency (gain) loss	7,143	(3,898)	(317)
Deferred income taxes	(6,548)	(11,807)	(5,732)
Share-based compensation	5,630	3,913	3,672
Non-cash interest expense and discount amortization	19,612	17,202	9,320
Inventory obsolescence	5,212	6,781	3,587
Change in fair value of warrant liability	(172)	28,027	
Other non-cash items affecting earnings	1,871	2,062	861
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable	(3,790)	425	(5,007)
Inventories	(17,349)	(13,927)	(18,222)
Accounts payable and accruals	2,348	497	794
Other current assets and liabilities	(307)	(870)	3,372
Other non-current assets and liabilities	1,710	(160)	36
Net cash provided by (used in) operating activities	2,889	2,291	(19,482)
Cash flows from investing activities:			
Acquisition-related cash payments	(2,328)	(7,656)	(12,730)
Consolidation of non-controlling interest			1,038
Additions of instruments	(13,838)	(12,339)	(18,155)
Purchases of property, plant, and equipment	(6,687)	(11,109)	(13,467)
Net cash used in investing activities	(22,853)	(31,104)	(43,314)
Cash flows from financing activities:			
Change in short-term debt	6,468	(3,506)	(2,122)
Repayments of long-term debt	(7,687)	(9,881)	(2,869)
Proceeds from issuance of long-term debt	11,361	6,030	10,198
Proceeds from the issuance of notes payable and warrants		49,332	52,406
Deferred financing costs	(3,534)		
Issuance of ordinary shares	819	2,882	8,874
Net cash provided by financing activities	7,427	44,857	66,487
Effect of exchange rate changes on cash and cash equivalents	(594)	577	310
(Decrease)/Increase in cash and cash equivalents	(13,131)	16,621	4,001
Cash and cash equivalents:			
Beginning of period	37,969	21,348	17,347
End of period	\$ 24,838	\$ 37,969	\$ 21,348

Edgar Filing: Tornier N.V. - Form 10-K

Non cash investing and financing transactions:

Fixed assets acquired pursuant to capital lease	\$	614	\$		\$
---	----	-----	----	--	----

Supplemental disclosure:

Income taxes (refunded) paid	\$	999	\$	(2,163)	\$	1,317
------------------------------	----	-----	----	---------	----	-------

Interest paid	\$	2,193	\$	1,854	\$	1,865
---------------	----	-------	----	-------	----	-------

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**Tornier B.V.****Consolidated Statements of Shareholders' Equity and Comprehensive Loss****(in thousands)**

	Ordinary shares		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In Capital	Other Comprehensive Income (Loss)	Deficit	
Balance at December 31, 2007	20,375	\$ 782	\$ 278,975	\$ 27,811	\$ (57,692)	\$ 249,876
Net loss					(33,004)	(33,004)
Foreign currency translation adjustments				(7,211)		(7,211)
Other				67		67
Total comprehensive loss						(40,148)
Accretion of non-controlling interest			(3,761)			(3,761)
Issuance of warrants related to debt financing, net of \$7,466 tax			21,812			21,812
Issuance of common stock related to acquisitions	303	14	5,138			5,152
Issuance of common stock related to stock option exercise	8		117			117
Other issuances of common stock	214	8	3,597			3,605
Share-based compensation			3,672			3,672
Balance at December 28, 2008	20,900	\$ 804	\$ 309,550	\$ 20,667	\$ (90,696)	\$ 240,325
Net loss					(54,619)	(54,619)
Foreign currency translation adjustments				(1,032)		(1,032)
Other				(146)		(146)
Total comprehensive loss						(55,797)
Accretion of non-controlling interest			(1,127)			(1,127)
Adoption of ASC Topic 740					(266)	(266)
Adoption of ASC Topic 815			(21,812)		863	(20,949)
Issuance of common stock related to stock option exercise	10		135			135
Conversion of mandatorily convertible debt	3,409	149	50,288			50,437
Other issuances of common stock	348	15	2,731			2,746
Share-based compensation			4,284			4,284
Balance at December 27, 2009	24,667	\$ 968	\$ 344,049	\$ 19,489	\$ (144,718)	\$ 219,788
Net loss					(38,814)	(38,814)
Foreign currency translation adjustments				(4,181)		(4,181)
Total comprehensive loss						(42,995)
Accretion of non-controlling interest			(679)			(679)
Conversion of warrants to ordinary shares, net of \$21,686 tax	3,780	143	63,156			63,299
Acquisition of C2M Medical, Inc.	1,031	41	23,159			23,200
Issuances of ordinary shares to related parties	44	2	980			982
Other issuances of ordinary shares	47	2	817			819
Share-based compensation			5,825			5,825
Balance at January 2, 2011	29,569	\$ 1,156	\$ 437,307	\$ 15,308	\$ (183,532)	\$ 270,239

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

1. Business Description

Tornier B.V., or the Company, is a global medical device company focused on surgeons that treat musculoskeletal injuries and disorders of the shoulder, elbow, wrist, hand, ankle and foot. Tornier refers to these surgeons as extremity specialists. Tornier sells to this extremity specialist customer base a broad line of joint replacement, trauma, sports medicine and biologic products to treat extremity joints. The Company's motto of "specialists serving specialists" encompasses this focus. In certain international markets, Tornier also offers joint replacement products for the hip and knee. Tornier currently sells over 80 product lines in approximately 35 countries.

Tornier has a tradition of innovation, intense focus on surgeon education, and commitment to advancement of orthopaedic technology since its founding approximately 70 years ago in France by René Tornier. Tornier's history includes the introduction of the world's first porous orthopaedic hip implant, the application of the Morse taper, which is a reliable means of joining modular orthopaedic implants and, more recently, the introduction of the reversed shoulder implant in the United States. This track record of innovation over the decades stems from our close collaboration with leading orthopaedic surgeons and thought leaders throughout the world.

The Company was acquired in 2006 by an investor group led by Warburg Pincus (Bermuda) Private Equity IX, L.P., or WP Bermuda, and medical device investors, including The Vertical Group, L.P., or The Vertical Group, and Split Rock Partners, L.P., and Douglas W. Kohrs, Tornier's President and Chief Executive Officer.

During 2007, the Company made several acquisitions that expanded its product offerings within the orthopaedic industry. The consolidated financial statements and accompanying notes present the consolidated results of the Company for each of the fiscal years in the three-year period ended January 2, 2011, December 27, 2009 and December 28, 2008.

The Company's global headquarters are located in Amsterdam, the Netherlands. The Company's U.S. headquarters are in Edina, Minnesota, and its U.S. sales and distribution operations are in Stafford, Texas. The Company has manufacturing, research and development, sales and distribution and administrative activities in Grenoble, France. The Company also has manufacturing operations in Ireland. The Company has other sales and distribution operations in Australia, Germany, Italy, The Netherlands, Spain, the United Kingdom, Scandinavia and Switzerland. The Company also has other research and development and quality and regulatory functions located in Warsaw, Indiana, San Diego, California and Beverly, Massachusetts.

In 2009, the Company consolidated its U.S. operations and closed quality and regulatory and sales and marketing functions in San Diego, California and manufacturing operations in Beverly, Massachusetts. See Note 18 for further details.

In 2008, the Company changed its fiscal reporting periods to 13-week quarters and a 52-week annual period, which ends on the Sunday nearest to and preceding December 31. The 2008 fiscal year began on January 1, 2008 and ended on December 28, 2008. This change did not have a material effect on the consolidated financial statements as compared to the prior years. During the first quarter of 2010 the Company added a 14th week to the quarterly reporting period in order to make up for past annual periods that included only 364 days under the 52-week annual period rather than a full 365 day annual period. As a result, the first quarter of 2010 includes an extra week of operations as compared to the first quarter of 2009.

Table of Contents

2. Significant Accounting Policies

Consolidation

The consolidated financial statements include the accounts of the Company and all of its wholly and majority owned subsidiaries. Additionally, the Company has consolidated the assets and liabilities of a variable interest entity (VIE), C2M Medical Inc. (C2M), for which the Company is deemed to be the primary beneficiary in 2009 and 2008. During 2010, the Company exercised its option to acquire the outstanding shares of C2M in exchange for Tornier ordinary shares. Upon exercise of the purchase option, a non-controlling interest in C2M no longer existed. The balance of the non-controlling interest was eliminated and the fair value of the shares issued in the acquisition, \$23.2 million, was recorded as a component of shareholders' equity. In consolidation, all material intercompany accounts and transactions are eliminated.

Use of Estimates

The consolidated financial statements are prepared in conformity with United States generally accepted accounting principles (GAAP) and include amounts that are based on management's best estimates and judgments. Actual results could differ from those estimates.

Foreign Currency Translation

The functional currencies for the Company and all of the Company's wholly owned subsidiaries are their local currencies. The reporting currency of the Company is the United States dollar. Accordingly, the consolidated financial statements of the Company and its international subsidiaries are translated into United States dollars using current exchange rates for the consolidated balance sheets and average exchange rates for the consolidated statements of operations and cash flows. Unrealized translation gains and losses are included in accumulated other comprehensive income (loss) in shareholders' equity. When a transaction is denominated in a currency other than the subsidiary's functional currency, the Company recognizes a transaction gain or loss in net earnings. Foreign currency transaction gains (losses) included in net earnings were \$(8.2) million, \$3.0 million, and \$1.7 million during the fiscal years ended January 2, 2011, December 27, 2009, and December 28, 2008, respectively. Included in the \$3.0 million of foreign currency transaction gain recognized in 2009 is \$3.9 million related to the revaluation of warrants carried as a liability on the consolidated balance sheets, which are denominated in a currency other than Tornier NV's functional currency.

Revenue Recognition

The Company derives its revenue from the sale of medical devices that are used by orthopaedic surgeons who treat diseases and disorders of extremity joints including the shoulder, elbow, wrist, hand, ankle and foot. The Company's revenue is generated from sales to two types of customers: healthcare institutions and distributors. Sales to healthcare institutions represent the majority of the Company's revenue. The Company utilizes a network of independent commission based sales agencies for sales in the United States and a combination of direct sales organizations, independent sales representatives and distributors for sales outside the United States. Generally, revenue from sales to healthcare institutions is recognized at the time of surgical implantation. The Company generally records revenue from sales to its distributors at the time the product is shipped to the distributor. Distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at time of shipment. The Company does not have any arrangements with distributors that allow for retroactive pricing adjustments. The Company's distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. In certain circumstances, the Company may accept sales returns from distributors and in certain situations in which the right of return exists, the Company estimates a

Table of Contents

2. Significant Accounting Policies (Continued)

reserve for sales returns and recognizes the reserve as a reduction of revenue. The Company bases its estimate for sales returns on historical sales and product return information including historical experience and trend information. The Company's reserve for sales returns has historically been immaterial. The Company charges its customers for shipping and handling and recognizes these amounts as part of revenue.

Shipping and Handling

Amounts billed to customers for shipping and handling of products are reflected in net sales and are not significant. Costs related to shipping and handling of products are expensed as incurred, are included in sales and marketing expense, and were \$4.3 million, \$3.4 million, and \$3.7 million for the fiscal years ended January 2, 2011, December 27, 2009, and December 28, 2008, respectively.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of three months or less. The carrying amount reported in the consolidated balance sheets for cash and cash equivalents is cost, which approximates fair value.

Accounts Receivable

Accounts receivable consist of trade customer receivables. The Company maintains an allowance for doubtful accounts for estimated losses in the collection of accounts receivable. The Company makes estimates regarding the future ability of its customers to make required payments based on historical credit experience, delinquency, and expected future trends. The majority of the Company's receivables are from health care institutions, many of which are government-funded. The Company's allowance for doubtful accounts was \$2.5 million, \$2.7 million and \$2.2 million at January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of accounts receivable. Management attempts to minimize credit risk by reviewing customers' credit history before extending credit and by monitoring credit exposure on a regular basis. The allowance for doubtful accounts is established based upon factors surrounding the credit risk of specific customers, historical trends, and other information. Collateral or other security is generally not required for accounts receivable. As of January 2, 2011, there were no customers that accounted for more than 10% of accounts receivable.

Advertising

The Company records advertising expenses as a component of sales and marketing expenses in the period in which they are incurred. The Company incurred \$2.4 million, \$1.9 million, and \$2.6 million in advertising costs during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

Royalties

The Company pays royalties to certain individuals and companies that have developed and retain the legal rights to the technology or have assisted the Company in the development of technology or new products. These royalties are based on sales and are reflected as a sales and marketing expense in the consolidated statements of operations.

Table of Contents**2. Significant Accounting Policies (Continued)****Inventories**

Inventories, net of reserves for obsolete and slow-moving goods, are stated at the lower of cost or market value. Cost is determined on a first-in, first-out (FIFO) basis. Inventory is held both within the Company and by third-party distributors on a consignment basis. Inventories consist of raw materials, work-in-process and finished goods. Finished goods inventories are held in the United States, Europe and Australia and consist primarily of implants. Manufactured and assembled instruments that have not been completed and placed in service are also included in the inventory balances and are reclassified as instruments, net in the consolidated balance sheets upon being made available for service.

Inventory balances consist of the following (in thousands):

	January 2, 2011	December 27, 2009
Raw materials	\$ 7,913	\$ 7,384
Work in process	5,356	7,773
Finished goods	64,256	53,464
Total	\$ 77,525	\$ 68,621

The Company regularly reviews inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, incurs charges to write down inventories to their net realizable value. The Company's review of inventory for excess and obsolete quantities is based primarily on the estimated forecast of product demand, production requirements, and introduction of new products. The Company recognized \$5.2 million, \$6.8 million, and \$3.6 million of expense for excess or obsolete inventory in earnings during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively. Additionally, the Company had \$14.7 million and \$13.3 million in inventory held on consignment at January 2, 2011 and December 27, 2009, respectively.

Property, Plant, and Equipment

Property, plant and equipment are carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on estimated useful lives of ten to 39 years for buildings and improvements and two to eight years for machinery and equipment. The cost of maintenance and repairs is expensed as incurred. The Company reviews property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than the asset's carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. No impairment losses were recognized during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008.

Instruments

Instruments are surgical tools used by surgeons during joint replacement and other surgical procedures to facilitate the implantation of the Company's products. Instruments are recognized as long-lived assets. Instruments and instrument parts that have not been placed in service are carried at cost, and are included as instruments in progress within instruments, net on the consolidated balance sheets. Once placed in service, instruments are carried at cost, less accumulated depreciation. Depreciation is computed using the straight-line method based on average estimated useful lives. Estimated useful lives are determined principally in reference to associated product life cycles, and average five years. The Company reviews instruments for impairment whenever events or changes in

Table of Contents**2. Significant Accounting Policies (Continued)**

circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than the asset's carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. No impairment losses were recognized during fiscal years ended January 2, 2011 or December 27, 2009. Instruments included in long-term assets on the consolidated balance sheets are as follows (in thousands):

	January 2, 2011	December 27, 2009
Instruments	\$ 58,356	\$ 47,376
Instruments in Progress	15,007	14,095
Accumulated depreciation	(30,985)	(21,021)
Instruments, net	\$ 42,378	\$ 40,450

The Company provides instruments to surgeons for use in surgeries and retains title to the instruments throughout the implantation process. As instruments are used as tools to assist surgeons, depreciation of instruments is recognized as a sales and marketing expense. Instrument depreciation expense was \$9.4 million, \$9.4 million and \$6.3 million during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

Goodwill

Goodwill is recognized as the excess of the purchase price over the fair value of net assets of businesses acquired. Goodwill is not amortized, but is subject to impairment tests. The Company performs impairment tests annually unless circumstances otherwise dictate. Based on the Company's single business approach to decision-making, planning and resource allocation, management has determined that the Company has one reporting unit for the purpose of evaluating goodwill for impairment. The Company performs its annual goodwill impairment test as of the first day of the fourth quarter of its fiscal year. Impairment tests are done by comparing the reporting unit's fair value to its carrying amount to determine if there is potential impairment. If the fair value of the reporting unit is less than its carrying value, an impairment loss is recorded to the extent that the implied fair value of the reporting unit's goodwill is less than the carrying value of the reporting unit's goodwill. The fair value of the reporting unit and the implied fair value of goodwill are determined based on widely accepted valuation techniques, primarily the income approach, as appropriate. The calculation of the fair value of the reporting unit involves significant management judgment, including the valuation of the Company's shares. At the time of the impairment test, the Company's shares were not traded in an active market, and therefore, this assumption was unobservable. No goodwill impairment losses were recorded during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008 as the fair value of the reporting unit significantly exceeded its carrying value.

Intangible Assets

Intangible assets with an indefinite life, including certain trademarks and trade names, are not amortized. The useful lives of indefinite-life intangible assets are assessed annually to determine whether events and circumstances continue to support an indefinite life. Intangible assets with an indefinite life are tested for impairment annually or whenever events or circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized if the carrying amount exceeds the estimated fair value of the asset. The amount of the impairment loss to be recorded would be determined based upon the excess of the asset's carrying value over its fair value. No impairment

Table of Contents

2. Significant Accounting Policies (Continued)

losses were recorded during the fiscal years ended January 2, 2011, December 27, 2009 or December 28, 2008, respectively.

Intangible assets with a finite life, including developed technology, customer relationships, and patents and licenses, are amortized on a straight-line basis over their estimated useful lives, ranging from 10 to 20 years. Intangible assets with a finite life are tested for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than the asset's carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. No impairment charges were recognized during the years ended January 2, 2011 or December 28, 2008. During the year ended December 27, 2009, an impairment charge of \$3.4 million was recognized when developed technology from acquired entities was abandoned and is included in amortization of intangible assets in the consolidated statements of operations.

Derivative Financial Instruments

All of the Company's derivative instruments are recorded in the accompanying consolidated balance sheets as either an asset or liability and are measured at fair value. The changes in the derivative's fair value are recognized currently in current period earnings.

Changes to the fair value of foreign currency derivative instrument economic hedges resulted in no impact on loss before income taxes for the fiscal year ended December 27, 2009, and \$0.7 million for the fiscal year ended December 28, 2008. These charges were classified as foreign currency transaction gain (loss) on the consolidated statements of operations. Any related derivative assets or liabilities are recorded as other current assets or other current liabilities, respectively, in the consolidated balance sheets. There were no outstanding foreign currency derivative instruments at January 2, 2011.

The Company also issued warrants in 2008 and 2009 for ordinary shares that are recognized as warrant liabilities on the consolidated balance sheets. Changes in the fair value of these warrants resulted in other non-operating gain of \$0.4 million for the year ended January 2, 2011. See footnote 7 for additional information on these warrants.

Research and Development

All research and development costs are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates in effect for the years in which the differences are expected to reverse. Valuation allowances for deferred tax assets are recognized if it is more likely than not that some component or all of the benefits of deferred tax assets will not be realized.

The Company adopted the provisions of FASB Accounting Standards Codification (ASC) Topic 740 related to accounting for uncertainty in income taxes on December 29, 2008. As a result of the implementation of these provisions, the Company recognized a \$0.3 million increase in the liability for unrecognized tax benefits, which was accounted for as an increase to the December 29, 2008 balance of accumulated deficit. The Company accrues interest and penalties related to unrecognized tax benefits in the Company's provision for income taxes. At January 2, 2011 and December 27, 2009, accrued interest and penalties were immaterial.

Table of Contents

2. Significant Accounting Policies (Continued)

Other Comprehensive Income (Loss)

Other comprehensive income (loss) refers to revenues, expenses, gains, and losses that under U.S. GAAP are included in comprehensive income (loss) but are excluded from net earnings, as these amounts are recorded directly as an adjustment to shareholders' equity. Other comprehensive income (loss) is comprised mainly of foreign currency translation adjustments. These amounts are presented in the consolidated statements of shareholders' equity and comprehensive loss.

Share-Based Compensation

The Company accounts for share-based compensation in accordance with ASC Topic 718, formerly Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payments Revised*, which requires share-based compensation cost to be measured at the grant date based on the fair value of the award and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. The determination of the fair value of share-based payment awards, such as options, on the date of grant using an option-pricing model is affected by the Company's share price, as well as assumptions regarding a number of complex and subjective variables, which include the expected life of the award, the expected share price volatility over the expected life of the award, expected dividend yield and risk-free interest rate.

Fair Value of Financial Instruments

The Company applies ASC Topic 820, which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC Topic 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC Topic 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that that market participants would use in pricing the asset or liability, and are to be developed based on the best information available in the circumstances.

When an active market for certain financial instruments does not exist, it may be appropriate to use unobservable inputs to determine fair value. The carrying value of the Company's cash and cash equivalents, accounts receivable, and accounts payable approximates the fair value of these financial instruments at January 2, 2011 and December 27, 2009. Assets and liabilities measured at fair value are done so on a recurring basis. U.S. GAAP requires fair value measurements to be classified and disclosed in one of the following three categories:

Level 1 Assets and liabilities with unadjusted, quoted prices listed on active market exchanges.

Level 2 Assets and liabilities determined using prices for recently traded assets and liabilities with similar underlying terms, as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 Assets and liabilities that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the asset or liability. The prices are determined using significant unobservable inputs or valuation techniques.

Table of Contents**2. Significant Accounting Policies (Continued)**

As of December 27, 2009, the Company had warrants that were classified as warrant liabilities and had a fair value of \$85.2 million. The fair value of the Company's share price is a significant input into this valuation, which was unobservable in the market. Therefore, these warrants are considered Level 3 instruments. The warrants were converted into ordinary shares during 2010. See Note 7 for further information.

Recent Accounting Pronouncements

In December 2009, the FASB issued Accounting Standards Update (ASU) 2009-17, *Consolidations (ASC Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*. ASU 2009-17 requires a qualitative approach to identifying a controlling financial interest in a variable interest entity (VIE), and requires ongoing assessment of whether an entity is a VIE and whether an interest in a VIE makes the holder the primary beneficiary of the VIE. The adoption of ASU 2009-17 in January 2010 did not have a material impact on the Company's consolidated financial statements.

In January 2010, the FASB issued ASU 2010-6, *Fair Value Measurements and Disclosures (ASC Topic 820): Improving Disclosures about Fair Value Measurements*, which requires reporting entities to make new disclosures about recurring or nonrecurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU2010-6 was effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for interim and annual periods beginning after December 15, 2010. The Company adopted the additional disclosures required for Level 1 and Level 2 fair value measurements in the first quarter of 2010. The Company will adopt Level 3 disclosures beginning in the first quarter of 2011.

3. Share-Based Compensation

Share-based awards are granted under the Company's stock option plan. Under this plan, options to purchase ordinary shares are the only type of share-based compensation awards granted. These options generally have graded vesting periods of four years and expire ten years after the grant date. The options are granted with exercise prices equal to the fair value of the Company's ordinary shares on the date of grant. The Company recognizes compensation expense for these options on a straight-line basis over the vesting period. Share-based compensation expense is included in cost of goods sold, sales and marketing, research and development, and general and administrative expenses on the consolidated statements of operations. Below is a summary of the allocation of share-based compensation (in thousands):

	Fiscal Year Ended		
	January 2, 2011	December 27, 2009	December 28, 2008
Cost of goods sold	\$ 536	\$ 77	\$ 341
Sales and marketing	1,800	1,306	1,034
General and administrative	2,861	2,250	2,051
Research and development	433	280	246
Total	\$ 5,630	\$ 3,913	\$ 3,672

The Company recognizes the fair value of an award of equity instruments granted in exchange for employee services as a cost of those services.

Table of Contents**3. Share-Based Compensation (Continued)**

The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of estimates, including the expected life of stock options, expected stock price volatility, the risk-free interest rate, and the expected dividend yield. The Company calculates the expected life of stock options using the SEC's allowed short-cut method. The expected stock price volatility assumption was estimated based upon historical volatility of the common stock of a group of the Company's peers that are publicly traded. The risk-free interest rate was determined using U.S. Treasury rates with terms consistent with the expected life of the stock options. Expected dividend yield is not considered, as the Company has never paid dividends and has no plans of doing so during the term of the options. The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data when available to estimate pre-vesting option forfeitures, and records stock-based compensation expense only for those awards that are expected to vest. All stock options are amortized and recognized as compensation expense on a straight-line basis over their respective requisite service periods, which are generally the vesting periods. Total compensation cost included in the consolidated statements of operations for employee share-based payment arrangements was \$5.1 million, \$3.4 million and \$3.3 million during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively. Additionally, \$0.6 million and \$0.4 million was included in inventory as a capitalized cost as of January 2, 2011 and December 27, 2009, respectively.

The weighted-average fair value of the Company's options granted to employees was \$11.03, \$7.23 and \$6.51 per share, in 2010, 2009 and 2008, respectively. During 2010, the Company granted 975,630 options to employees to purchase ordinary shares with an exercise price of \$22.50 per share and a weighted average fair value of \$11.03 per share. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

	2010	2009	2008
Risk-free interest rate	2.3%	1.8%	2.5%
Expected life in years	5.8	6.0	6.0
Expected volatility	49.8%	41.8%	35.1%
Expected dividend yield	0.0%	0.0%	0.0%

As of January 2, 2011, the Company had \$11.4 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted to employees under the stock option plan. That cost is expected to be recognized over a weighted-average service period of 2.7 years. Shares reserved for future compensation grants were 1.2 million and 0.1 million at January 2, 2011 and December 27, 2009, respectively. Exercise prices for options outstanding at January 2, 2011, ranged from \$13.39 to \$22.50.

Table of Contents**3. Share-Based Compensation (Continued)**

A summary of the Company's employee stock option activity is as follows:

	Shares (In Thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In Years)
Outstanding at December 31, 2007	1,805	13.89	8.9
Granted	544	16.98	
Exercised	(9)	13.44	
Forfeited or expired	(62)	13.62	
Outstanding at December 28, 2008	2,278	14.61	8.2
Granted	507	16.95	
Exercised	(10)	13.50	
Forfeited or expired	(124)	14.40	
Outstanding at December 27, 2009	2,651	15.06	7.6
Granted	992	22.50	
Exercised	(32)	15.32	
Forfeited or expired	(79)	15.81	
Outstanding at January 2, 2011	3,532	17.02	7.4

During the years ended January 2, 2011 and December 27, 2009, the Company issued 21,000 and 58,833 options, respectively, to non-employees in exchange for consulting services. No options were issued to non-employees during the year ended December 28, 2008. The options issued in 2010 and 2009 had weighted-average exercise prices of \$22.50 and \$16.89, respectively. Approximately 154,770 of these non-employee options were exercisable at January 2, 2011. 2,419 of these options were exercised in 2010. These options have vesting periods of either 2 or 4 years and expire 10 years after the grant date. The measurement date for options granted to non-employees is often after the grant date, which often requires updates to the estimate of fair value until the services are performed. The weighted-average fair value of each non-employee option granted was \$10.44 and \$7.59 in 2010 and 2009, respectively. The amount of expense related to non-employee options was \$0.6 million, \$0.5 million and \$0.4 million for the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

Table of Contents**4. Property, Plant, and Equipment**

Property, plant, and equipment balances are as follows (in thousands):

	January 2, 2011	December 27, 2009
Land	\$ 2,195	\$ 2,337
Building and improvements	10,087	10,630
Machinery and equipment	20,420	19,604
Furniture, fixtures, and office equipment	22,066	16,092
Software	4,134	4,035
Construction in progress	129	3,079
	59,031	55,777
Accumulated depreciation	(25,351)	(20,701)
Property, plant, and equipment, net	\$ 33,680	\$ 35,076

In 2009, the Company leased a new manufacturing facility in Ireland. In conjunction with moving into the leased building, the Company made approximately \$2.4 million in leasehold improvements that are included in fixed assets as of December 27, 2009.

Depreciation expense recorded on property, plant, and equipment was \$6.1 million, \$5.7 million and \$5.3 million during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

During the fiscal year ended December 27, 2009, the Company's majority-owned subsidiary, SCI Calyx, acquired a combined manufacturing and office facility in Grenoble, France, for approximately \$6.1 million.

5. Goodwill and Other Intangible Assets

The following table summarizes the changes in the carrying amount of goodwill for the fiscal years ended January 2, 2011 and December 27, 2009 (in thousands):

Balance at December 28, 2008	\$ 130,632
Contingent payment on acquisition	3,836
Goodwill from acquisition	171
Other	76
Foreign currency translation	2,234
Balance at December 27, 2009	136,949
Contingent payment on acquisition	723
Foreign currency translation	(5,842)
Balance at January 2, 2011	\$ 131,830

The goodwill balance at January 2, 2011 contains \$13.9 million of goodwill that qualifies for future tax deductions.

Table of Contents**5. Goodwill and Other Intangible Assets (Continued)**

The components of identifiable intangible assets are as follows (in thousands):

	Gross Value	Accumulated Amortization	Net Value
Balances at January 2, 2011			
Intangible assets subject to amortization:			
Developed technology	\$ 76,561	\$ (24,164)	\$ 52,397
Customer relationships	61,838	(18,275)	43,563
Licenses	3,965	(1,492)	2,473
Other	1,645	(967)	678
Intangible assets not subject to amortization:			
Tradename	9,913		9,913
Total	\$ 153,922	\$ (44,898)	\$ 109,024

	Gross Value	Accumulated Amortization	Net Value
Balances at December 27, 2009			
Intangible assets subject to amortization:			
Developed technology	\$ 79,252	\$ (19,134)	\$ 60,118
Customer relationships	65,360	(15,017)	50,343
Licenses	3,780	(470)	3,310
Other	2,172	(1,404)	768
Intangible assets not subject to amortization:			
Tradename	10,682		10,682
Total	\$ 161,246	\$ (36,025)	\$ 125,221

All finite-lived intangible assets have been assigned an estimated useful life and are amortized on a straight-line basis over the number of years that approximates the assets' respective useful lives (ranging from 10 to 20 years). The weighted-average amortization periods, by major intangible asset class, are as follows:

	Weighted-Average Amortization Period (In Years)
Developed technology	13
Customer relationships	15
Licenses	6

Total amortization expense for finite-lived intangible assets was \$11.5 million and \$15.2 million during the fiscal years ended January 2, 2011 and December 27, 2009, respectively. Amortization expense is recorded as amortization of intangible assets in the consolidated statements of operations.

Table of Contents**5. Goodwill and Other Intangible Assets (Continued)**

Estimated annual amortization expense for fiscal years ending 2011 through 2015 is as follows (in thousands):

	Amortization Expense
2011	\$ 10,268
2012	10,117
2013	10,073
2014	10,030
2015	10,023

6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	January 2, 2011	December 27, 2009
Accrued payroll & related expenses	\$ 14,887	\$ 15,578
Income, VAT, and other taxes	3,972	2,997
Accrued royalties	6,435	5,620
Other accrued liabilities	9,326	11,385
	\$ 34,620	\$ 35,580

7. Notes Payable and Warrants to Issue Ordinary Shares

In April 2009, the Company issued notes payable in the amount of €37 million (approximately \$49.3 million) to a group of investors that included existing shareholders, new investors and management of the Company. The notes carry a fixed interest rate of 8.0% with interest payments accrued in kind semi-annually. The notes mature in March 2014.

These notes payable have a cross default clause in which any event of default under the terms of the Company's other debt arrangements also are defined as an event of default under the terms of these notes payable. In 2009, there were no events of default. Additionally, \$0.2 million of debt issuance costs related to this issuance have been capitalized and are included in other non-current assets on the consolidated balance sheet and are being recognized as additional interest expense over the term of the notes.

In connection with the note agreement, the Company also issued a total of 2.9 million warrants to purchase ordinary shares at an exercise price of \$16.98 per share. These warrants have a strike price in U.S. dollars; however, the functional currency of the parent company issuing the notes is the Euro. As a result, GAAP requires that these warrants be classified as liabilities on the balance sheet and recorded at fair value. The fair value of the warrants at the date of issuance was \$9.87 per warrant, or \$29.1 million, and was determined using a Black-Scholes option pricing model, which takes into account various assumptions such as share price volatility, risk free interest rate and expected term. Share price volatility is determined based on the volatility of various peers of the Company. The fair value of the warrants as of December 27, 2009 was approximately \$14.49 per warrant. The Company recorded a \$13.5 million loss in other non-operating expense, net related to the change in the fair value of the warrants in 2009. The Company recorded a \$2.7 million foreign currency transaction gain in 2009. This gain is related to the change in exchange rates, and is recorded in foreign currency transaction gain

Table of Contents**7. Notes Payable and Warrants to Issue Ordinary Shares (Continued)**

(loss) in the consolidated statements of operations. A summary of the assumptions used to determine the fair value on the date of issuance and December 27, 2009 is as follows:

	Date of Issuance	December 27, 2009
Fair value of underlying stock	\$ 16.98	\$ 22.50
Volatility	44.34%	44.43%
Risk-free interest rate	2.78%	3.55%
Expected term (in years)	10	9
Dividend yield	0%	0%

The Company recorded the warrants as liabilities with an offsetting debt discount recorded as a reduction of the carrying value of the notes. The debt discount will be amortized as additional interest expense over the life of the notes. GAAP requires that the allocation of proceeds be allocated first to the fair value of the warrant liability with the residual allocated to the outstanding debt. The debt discount was \$21.7 million (net of tax of \$7.4 million) on the issuance date. The Company recorded \$5.8 million and \$4.6 million of additional interest expense related to the amortization of discount during the years ended January 2, 2011 and December 27, 2009, respectively. The Company also recognized \$4.3 million and \$3.1 million of non-cash interest expense related to the stated 8% interest rate on the notes during the years ended January 2, 2011 and December 27, 2009, respectively. Together with the stated interest and amortization of debt discount, the effective interest rate recognized related to the notes payable was approximately 20.6% and 19.7% at January 2, 2011 and December 27, 2009, respectively.

In February 2008, the Company issued notes payable in the amount of € 34.5 million (approximately \$52.4 million) to a group of investors that included existing shareholders and management of the Company. The notes carry a fixed interest rate of 8.0% with interest payments accrued in-kind. The notes mature on February 28, 2013. These notes payable also have a cross default clause in which any event of default under the terms of the Company's other debt arrangements also are defined as an event of default under the terms of these notes payable.

Also, in connection with the 2008 note agreement, the Company issued a total of 3.1 million warrants to purchase ordinary shares at a price of \$16.98 per share. At issuance, the Company accounted for the warrants separately from the debt and allocated the proceeds received to the debt and the warrants based on their relative fair values. As a result, the warrants were valued at \$21.8 million (net of tax of \$7.5 million) as an increase to equity with an offsetting discount of \$29.3 million recorded as a reduction of the carrying value of the notes.

Upon the Company's adoption of ASC Topic 815 on December 29, 2008, the Company determined that the warrants no longer qualified to be recognized as equity under ASC Topic 815 as they were determined to not be indexed to the Company's stock as prescribed by ASC Topic 815 due to the fact that the warrants are denominated in a currency other than their functional currency. On December 29, 2008, the warrants, upon adoption of ASC Topic 815, were reclassified from equity to warrant liability at the then fair value of \$28.1 million and marked to market through the consolidated statement of operations subsequent to that date. The value of the warrants decreased by \$1.2 million (\$0.9 million net of tax) from the warrants' issuance date to the adoption date of ASC Topic 815 on December 29, 2008. As of December 29, 2008, the cumulative effect of adopting ASC Topic 815 was recognized as a reduction to additional paid-in capital of \$21.8 million (\$29.3 million net of tax) to reclassify the warrants from equity to warrant liability and a decrease in accumulated deficit of \$0.9 million recognized as a cumulative effect of a change in accounting principle to reflect the change in the value of the warrants between their issuance date and December 29, 2008.

Table of Contents**7. Notes Payable and Warrants to Issue Ordinary Shares (Continued)**

For the year ended December 27, 2009 the Company recognized a loss on the change in fair value of the warrant liability of \$14.5 million, in non-operating expense, net related to the warrants issued in 2008. Additionally, the Company recognized \$1.2 million of foreign currency transaction gains on the warrant liability for the year ended December 27, 2009. Under ASC Topic 815, the warrants will be carried at fair value and adjusted at each reporting period to fair value through current period earnings. As of December 27, 2009, the warrant liability had a fair value of \$42.6 million. The impact of adoption of ASC Topic 815 was as follows:

	Balance Prior to Adoption	Impact of Adoption	Balance After Adoption
Warrant liabilities	\$	\$ (28,119)	\$ (28,119)
Non-current deferred tax assets		7,170	7,170
Additional paid-in capital	(313,311)	21,812	(291,499)
Accumulated deficit	94,473	(863)	93,610

The fair value was determined using the Black-Scholes Option Pricing Model. The following table summarizes the assumptions used to determine fair value on the date of issuance, the date of adoption of ASC Topic 815, and as of December 27, 2009:

	Date of Issuance	December 29, 2008	December 27, 2009
Fair value of underlying stock	\$ 16.98	\$ 16.98	\$ 22.50
Volatility	39.38%	42.35%	43.46%
Risk-free interest rate	3.53%	2.46%	3.55%
Expected term (in years)	10	9	8
Dividend yield	0%	0%	0%

The Company is amortizing the value of the debt discount as additional interest expense over the term of the notes. The Company recorded \$5.1 million, \$5.4 million and \$4.7 million of additional interest expense related to the amortization of discount during 2010, 2009 and 2008, respectively. The Company also recognized \$4.4 million, \$4.2 million and \$3.4 million in 2010, 2009 and 2008, respectively, related to the stated 8% interest rate on the notes. Together with the stated interest and amortization of debt discount, the effective interest rate recognized related to the notes payable was approximately 20.8% and 19.9% at January 2, 2011 and December 27, 2009, respectively.

In May 2010 the Company executed agreements with 100% of the warrant holders that acquired warrants under the February 2008 and April 2009 note payable and warrant issuances to exchange their outstanding warrants for the Company's ordinary shares. Each warrant holder agreed to exchange their warrants under the February 2008 and April 2009 agreements for ordinary shares of the Company at an exchange ratio of 0.6133 and 0.6410 respectively. In order to settle the warrant liabilities related to the February 2008 and April 2009 warrant issuances, the Company issued 1,894,076 and 1,885,624 ordinary shares, respectively. The Company determined the fair value of its ordinary shares to be \$22.50 per share at the date of the exchange which resulted in the issuance of shares with a total value of \$85.0 million. This amount, net of \$21.7 million of tax was recognized as an increase to equity at the time of the exchange. The Company recognized a gain on the change in fair value of the warrant liability of \$0.2 million in non-operating expense, net during the year ended January 2, 2011 to adjust the carrying value of the warrant liability to the final settlement amount. The Company also recognized \$11.6 million of foreign currency transaction loss on the warrant liability for the year ended January 2, 2011. This transaction settled the warrant liability of \$85.2 million included in the consolidated balance sheet at December 27, 2009.

Table of Contents**7. Notes Payable and Warrants to Issue Ordinary Shares (Continued)**

Changes in the carrying value of warrants are as follows:

Warrant value at December 28, 2008	\$ 29,277
Impact of adoption of ASC Topic 815 fair value adjustment	(1,159)
Issuance of 2009 warrants at fair value	29,070
Change in fair value during the year	28,027

Warrant value at December 27, 2009	\$ 85,215
------------------------------------	-----------

Change in fair value during the period	(172)
--	-------

Fair value of shares issued to settle liability and recognized in equity on May 27, 2010	\$ 85,043
--	-----------

Warrant value at January 2, 2011	\$
----------------------------------	----

Notes payable as outstanding are as follows:

	January 2, 2011	December 27, 2009
Gross notes payable	\$ 114,357	\$ 113,793
Discount to notes payable	(30,096)	(44,258)
Net notes payable	\$ 84,261	\$ 69,535

The fair value of the Company's Notes Payable as of January 2, 2011 and December 27, 2009 was approximately \$79.8 million and \$63.7 million, respectively. The fair value was determined using a discounted cash flow analysis, calculated using management's best estimates of the key assumptions, primarily the discount rate. As a result of various factors, including the Company's financial position, the assumptions used are unobservable in the market place.

8. Other Long-Term Debt

The Company's European subsidiaries have established unsecured lines of credit totaling \$21.9 million and \$15.3 million at January 2, 2011 and December 27, 2009, respectively. Borrowings under these lines were \$15.4 and \$8.1 million at January 2, 2011 and December 27, 2009, respectively. Borrowings under these lines have variable interest rates based on the Euro Overnight Index Average plus 1.3% or a three-month Euro plus 0.5%-3.0%.

The Company's U.S.-based subsidiary has established a \$10 million and \$6.0 million secured line of credit at January 2, 2011 and December 27, 2009. This line of credit expires in July 2012 and is callable by the bank at any time. Also, the line is secured by working capital and equipment. Borrowings under the line were \$5.2 million and zero at January 2, 2011 and December 27, 2009, respectively. Borrowings under the line of credit bear interest at a 30-day LIBOR plus 2.25%, with a floor interest rate of 5%. This line contains customary affirmative and negative covenants and events of default. As of January 2, 2011, the Company's U.S. subsidiary was subject to a covenant to maintain no less than \$39.0 million of tangible net worth. As of January 2, 2011, the Company was also subject to a covenant to maintain a maximum debt to tangible net worth ratio of 1.50. The covenants relate to the U.S. subsidiary's ratios only. The Company was in compliance with all covenants as of January 2, 2011.

The Company has a mortgage secured by the Company's U.S. subsidiary's office building in Stafford, Texas. This mortgage had an outstanding amount of \$1.3 million and \$1.4 million at January 2, 2011 and December 27, 2009, respectively. This mortgage bears a fixed interest rate of 6.7%.

Table of Contents**8. Other Long-Term Debt (Continued)**

The Company also has a mortgage secured by an office building in Grenoble, France. This mortgage had an outstanding balance of \$5.0 million and \$6.0 million at January 2, 2011 and December 27, 2009, respectively. This mortgage bears a fixed interest rate of 4.9%.

The Company's U.S. subsidiary has long-term debt secured by its working capital, and equipment. This debt had an outstanding amount of \$0.3 million and \$1.2 million at January 2, 2011 and December 27, 2009, respectively. This debt accrues interest based on a variable rate of LIBOR plus 2.25%.

The Company's international subsidiaries have other long-term secured and unsecured notes totaling \$24.2 million and \$21.3 million at January 2, 2011 and December 27, 2009, respectively, with initial maturities ranging from 3 to 10 years. A portion of these notes have fixed interest rates that range from 2.9% to 7.5%. The remaining notes carry a variable interest rate based on LIBOR, plus 1.2%, or a three-month Euro, plus 0.3% to 1.5%.

One of the Company's 51%-owned and consolidated subsidiaries borrowed \$2.4 million from a member of the Board of Directors who is also a 49% owner of the consolidated subsidiary. This loan was used to partially fund the purchase of real estate in Grenoble, France, to be used as a future manufacturing facility. Interest on the debt is variable based on three-month Euro plus 0.5%. The non-controlling interest in this subsidiary is deemed immaterial to the consolidated financial statements.

A summary of debt is as follows (in thousands):

	January 2, 2011	December 27, 2009
Lines of credit	\$ 20,639	\$ 15,271
Mortgages	6,342	7,438
Other term debt	24,522	22,464
Shareholder debt	2,356	1,015
Total debt	53,859	46,188
Less current portion	(28,392)	(23,299)
Long-term debt	\$ 25,467	\$ 22,889

Aggregate maturities of debt for the next five years are as follows (in thousands):

2011	\$ 7,754
2012	7,194
2013	5,385
2014	3,893
2015	2,389
Thereafter	6,606

The Company was also party to certain mandatorily convertible debt agreements allowing for conversion into 3.4 million common shares at a conversion price of \$14.70 as of July 18, 2009. These instruments were in their legal form debt, and therefore, we recognized a \$47.8 million liability within the consolidated balance sheet in 2008. In 2009, we satisfied the debt through the share conversion. The agreements contained a beneficial conversion feature as the fixed conversion price of the bonds was less than the fair value of the common stock on the issuance date. The beneficial conversion feature is accreted through interest expense and resulted in additional interest expense of \$0.6 million and \$1.2 million for the years ended December 27, 2009 and December 28, 2008, respectively. The

Table of Contents**8. Other Long-Term Debt (Continued)**

agreement had no payment terms, did not accrue interest, and, in no circumstances other than liquidation, required the Company to cash settle in part or in full.

Additionally, in 2007, the Company purchased Axya. At the time of the acquisition, the Company's majority shareholder entered into an agreement with another shareholder of the Company to either issue additional mandatorily convertible zero coupon bonds or decrease the conversion price of the zero coupon bonds, in which additional shares would be obtained upon conversion, if the performance of Axya did not meet certain thresholds. The arrangement represented a modification to the conversion terms of the mandatorily convertible bonds, as under either settlement scenario, the result is that the holder could receive more shares than originally entitled upon mandatory conversion. The Company estimated the fair value of the modification and recorded as an increase to equity with an offsetting amount recorded as a discount to the carrying value of the mandatorily convertible bonds. This discount is accreted to the bonds' par value over the remaining term of the bonds as interest expense. The fair value of the modification was determined to be \$0.6 million at the date of modification. The Company recognized \$0.1 million and \$0.3 million in additional interest expense in 2009 and 2008, respectively as a result of this modification.

All of the outstanding mandatorily convertible debt agreements were converted in accordance with the terms of the agreements during 2009.

9. Retirement and Postretirement Benefit Plans

The Company's French subsidiary is required by French government regulations to provide certain lump-sum retirement benefits that qualify as a defined benefit retirement plan. The French regulations do not require funding of this liability in advance and as a result there are no plan assets associated with this defined-benefit plan. The Company has a liability of \$1.7 million and \$1.5 million recorded at January 2, 2011 and December 27, 2009, respectively. The related periodic benefit expense was immaterial in all periods presented.

10. Income Taxes

The components of earnings (loss) before taxes for the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, consist of the following (in thousands):

	2010	2009	2008
United States loss	\$ (6,526)	\$ (18,444)	\$ (24,174)
Rest of the world loss	(38,104)	(51,655)	(15,230)
Loss before taxes	\$ (44,630)	\$ (70,099)	\$ (39,404)

The income tax benefit (provision) for the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, consists of the following (in thousands):

	2010	2009	2008
Current benefit (provision):			
United States	\$ (433)	\$ 2,884	\$
Rest of the world	539	553	(196)
Deferred benefit	5,015	10,976	5,423
Total benefit for income taxes	\$ 5,121	\$ 14,413	\$ 5,227

Table of Contents**10. Income Taxes (Continued)**

A reconciliation of the United States statutory income tax rate to the Company's effective tax rate for the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, is as follows:

	2010	2009	2008
Income tax provision at U.S. statutory rate	34.0%	34.0%	34.0%
Change in valuation allowance	(11.9)	(6.8)	(22.9)
Non-taxed interest income on participating loan	0.3	0.2	1.0
State and local taxes	(0.1)	0.1	2.2
R&D credits	0.6	1.0	1.3
Unrecognized interest deduction	(2.5)	(1.4)	(1.6)
Impact of foreign income tax rates	(5.8)	(5.1)	(0.2)
Non-deductible expenses	(0.4)	(0.3)	
Other	(2.7)	(1.1)	(0.5)
Total	11.5%	20.6%	13.3%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established valuation allowances for deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit.

During 2008, the Company reversed \$2.9 million of previously recognized valuation allowance related to accumulated net operating losses of one of its French subsidiaries. Of the \$2.9 million, \$2.4 million was recorded as a reduction of goodwill as it related to valuation allowances recorded as a part of one of the Company's 2007 acquisitions. The Company has \$26.9 million, \$22.8 million and \$17.4 million of valuation allowance recorded at January 2, 2011, December 27, 2009 and December 28, 2008, respectively. If any amounts reverse, the reversals would be recognized in the income tax provision in the period of reversal. The Company recognized \$5.2 million, \$4.8 million, and \$9.1 million of the valuation allowance as a tax expense during the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

Table of Contents**10. Income Taxes (Continued)**

The components of deferred taxes for the fiscal years ended January 2, 2011 and December 27, 2009, consist of the following (in thousands):

	2010	2009
Deferred tax assets:		
Net operating loss carryforwards	\$ 18,631	\$ 19,937
Warrant liabilities		21,730
Intangible assets	225	6,303
Transaction costs	250	955
Exchange rate changes		1,235
Stock options	6,449	4,072
Accruals and other provisions	9,711	7,914
Total deferred tax assets	35,266	62,146
Less: valuation allowance	(26,974)	(22,816)
Total deferred tax assets after valuation allowance	8,292	39,330
Deferred tax liabilities:		
Intangible assets	(24,325)	(34,040)
Foreign currency exchange rate changes	(248)	
Debt discount	(7,636)	(11,286)
Depreciation	(1,782)	(2,022)
Other		(149)
Total deferred tax liabilities	(33,991)	(47,497)
Total net deferred tax liabilities	\$ (25,699)	\$ (8,167)

The majority of the Company's income tax benefit recognized in 2010 relates to the reversal of the deferred tax liabilities related to the debt discount on the notes payable issued in 2008 and 2009.

Net operating loss carryforwards totaling approximately \$37 million and \$31 million at January 2, 2011 are available to reduce future taxable earnings of the Company's consolidated U.S. subsidiaries and certain European subsidiaries, respectively. These net operating loss carryforwards include \$29 million with no expiration date; the remaining carryforwards have expiration dates between 2010 and 2029.

The Company has recorded a long-term liability of approximately \$1.3 million and \$0.3 million at January 2, 2011 and December 27, 2009, respectively, which represents the Company's best estimate of the potential additional tax liability related to certain tax positions from unclosed tax years in certain of its subsidiaries. To the extent that the results of any future tax audits differ from the Company's estimate, changes to tax uncertainties outside the measurement period will be reported as adjustments to income tax expense.

The total amount of net unrecognized tax benefits that, if recognized, would affect the tax rate was \$4.7 million at January 2, 2011. Management believes that it is reasonably possible the total amounts of unrecognized tax benefits will decrease between zero and \$0.5 million due to the resolution of certain issues resulting from the expiration of the statute of limitations in the U.S. within the 12 months subsequent to January 2, 2011. The Company files income tax returns in the U.S. federal jurisdiction and in various U.S. state and foreign jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2007. There are currently tax examinations in progress in Germany and the United States. The

Table of Contents**10. Income Taxes (Continued)**

Company does not expect the results of these examinations to have a material impact to the financial statements in future years. A reconciliation of the beginning and ending balances of the total amounts of unrecognized tax benefits is as follows (in thousands):

A reconciliation of the beginning and ending balances of the total amounts of unrecognized tax benefits is as follows (in thousands):

Gross unrecognized tax benefits at December 27, 2009	\$ 2,988
Increase for tax positions in prior years	2,032
Decrease for tax positions in prior years	(1,305)
Settlements	
Increase for tax positions in current years	1,110
Foreign currency translation	(118)
Gross unrecognized tax benefits at January 2, 2011	\$ 4,707

11. Capital Stock and Earnings Per Share

The Company had 29.6 million and 24.7 million ordinary shares issued and outstanding as of January 2, 2011 and December 27, 2009, respectively.

The dividend rights of the mandatorily convertible debt and ordinary shares are identical. In addition, the shares issuable under the convertible debt agreement have been included as outstanding common shares for the purpose of computing basic earnings per share in accordance with GAAP in all years presented for which these notes were outstanding.

The Company had 3.7 million, 2.8 million and 2.4 million employee stock options outstanding at January 2, 2011, December 27, 2009 and December 28, 2008, respectively. Also outstanding are zero and 6.0 million warrants as of January 2, 2011 and December 27, 2009, respectively. All warrants were issued in 2008 and 2009 in relation to long-term debt financing agreements (see Note 7). Outstanding options and warrants representing 3.7 million, 8.8 million, and 5.5 million shares are not included in diluted earnings per share for the fiscal years ended January 2, 2011, December 27, 2009 and December 28, 2008, because the Company recorded a net loss in all periods and, therefore, including these instruments would be anti-dilutive.

12. Segment and Geographic Data

The Company has one reportable segment, orthopedic products, which includes the design, manufacture, and marketing of reconstructive joint devices and other related products. The Company's geographic regions consist of the United States, Europe, and other areas. Long-lived assets are those assets located in each region. Revenues attributed to each region are based on the location in which the products were sold.

Table of Contents**12. Segment and Geographic Data (Continued)**

Net sales by geographic region are as follows (in thousands):

	Year Ended		
	January 2, 2011	December 27, 2009	December 28, 2008
Net sales by geographic region:			
United States	\$ 127,762	\$ 112,588	\$ 91,106
France	47,324	46,331	43,206
Other International	52,292	42,453	43,058
Total	\$ 227,378	\$ 201,462	\$ 177,370

Net sales by product category are as follows (in thousands):

	Year Ended		
	January 2, 2011	December 27, 2009	December 28, 2008
Net sales by product type:			
Upper extremities	\$ 139,175	\$ 125,454	\$ 108,829
Lower extremities	23,629	20,417	18,167
Sports medicine and biologics	13,210	6,593	2,513
Total extremities	176,014	152,464	129,509
Large joints and other	51,364	48,998	47,861
Total	\$ 227,378	\$ 201,462	\$ 177,370

Long-lived tangible assets, including instruments, property, plant, and equipment are as follows (in thousands):

	January 2 2011	December 27 2009
Long-lived assets:		
United States	\$ 21,381	\$ 20,189
France	40,761	42,383
Other International	13,916	12,954
Total	\$ 76,058	\$ 75,526

13. Leases

Future minimum rental commitments under non-cancelable operating leases in effect as of January 2, 2011, are as follows (in thousands):

2011	\$ 4,691
2012	3,189
2013	1,950
2014	1,846
2015	1,725
Thereafter	4,122
Total	\$ 17,523

Table of Contents**13. Leases (Continued)**

Total rent expense for the years ended January 2, 2011, December 27, 2009 and December 28, 2008 was \$3.3 million, \$3.7 million and 3.4 million, respectively.

Future lease payments under capital leases are as follows (in thousands):

2011	\$ 441
2012	429
2013	227
2014	24
2015	
Thereafter	
Total minimum lease payments	1,121
Less amount representing interest	(86)
Present value of minimum lease payments	1,035
Current portion	(394)
Long-term portion	\$ 641

Fixed assets that are recorded as capital lease assets consist of machinery and equipment, and have a carrying value of \$1.4 million (\$2.0 million gross value, less \$0.6 million accumulated depreciation) at January 2, 2011 and \$1.8 million (\$2.2 million gross value, less \$0.4 million accumulated depreciation) at December 27, 2009. Amortization of capital lease assets is included in depreciation expense in the consolidated financial statements.

14. Non-Controlling Interests

Tornier currently markets the Piton Knotless Anchor (Piton), an arthroscopic technology for rotator cuff repair. The Piton was based on technology developed by Sapphire Medical, Inc. (Sapphire). In April 2007, C2M acquired all the assets related to the Piton technology from Sapphire. C2M is a company founded and owned by certain current shareholders of Tornier. Tornier had no equity ownership interest in C2M.

Under the terms of the purchase agreement between C2M and Sapphire, C2M paid Sapphire \$7.5 million upon execution of the transaction. C2M also agreed to pay Sapphire a \$5 million milestone payment upon completion of 75 surgeries using the Piton and a separate \$7.5 million milestone payment once the Piton was commercially launched to the sales force. These milestones were paid by C2M during 2008. Additionally, C2M agreed to pay Sapphire an earnout equal to 25% of Piton sales for the first three years after launch.

In January of 2008, Tornier began negotiating a licensing agreement with C2M for use of its Piton technology to launch as an anchor product in Tornier's newly developed sports medicine product portfolio. In June of 2008, Tornier executed an exclusive worldwide license agreement with C2M for use of the Piton technology. The terms of the agreement called for Tornier to assume the remaining obligation of C2M under their purchase agreement with Sapphire related to future earnout payments equal to 25% of Piton sales for the three-year period after product launch. C2M had the right to terminate the license agreement at any time after 18 months from the execution of the license. The terms of the license also included an option purchase agreement (the Option Agreement) that allowed the Company to purchase 100% of the common stock of C2M once cumulative Piton sales reach \$5 million or C2M terminates the license (the Call Option). Additionally, the license included a clause, whereby C2M could require the Company to purchase 100% of C2M's common stock if sales of the

Table of Contents

14. Non-Controlling Interests (Continued)

Piton anchor products exceed \$5 million (the Put Option). Under both the Call Option and the Put Option, the purchase price of C2M would be equal to the paid-in capital of C2M and is required to be paid in Tornier B.V. ordinary shares. The paid-in capital of C2M as of December 2008 and 2009 was approximately \$23.2 million, which consisted of the purchase price paid to Sapphire for the Piton technology, including milestones paid, and an additional amount of capital to fund development activities.

The Company determined that C2M was a VIE as of June 2008. The Option Agreement allowed for Tornier to purchase C2M at a fixed price regardless of the actual performance of the Piton products. As a result, C2M did not have the right to receive expected residual returns that would instead be enjoyed by Tornier. Tornier was considered the primary beneficiary of C2M because it had the obligation to absorb the majority of the expected losses and the right to absorb the majority of the expected returns. As a result, Tornier was required to consolidate C2M. This conclusion was reached due to the existence of the Put Option and Call Option to acquire C2M at a price that was fixed upon entry into the license agreement. Accordingly, the financial position and results of operations of C2M have been included in the consolidated financial statements from the date of execution of the license agreement. The liabilities recognized as a result of consolidating C2M consist primarily of the fair value of the obligations C2M had under its purchase agreement with Sapphire. As of January 2, 2011 and December 27, 2009, the only material liability recognized relates to the estimated remaining earnout payments due under the original Sapphire purchase agreement. Tornier is required to make these earnout payments on behalf of C2M in accordance with the license agreement. The assets of C2M consist of only cash used to fund ongoing operations and the Piton technology intangible asset.

Pursuant to authoritative guidance, the equity interests in C2M not owned by the Company are reported as non-controlling interests on the consolidated balance sheet of the Company. Losses incurred by C2M are charged to the Company and to the non-controlling interest holders based on their ownership percentage. Prior to the acquisition of the noncontrolling interest by the Company, the non-controlling interest holders held 100% of the equity interests in C2M, and therefore, none of the results of operations are allocated to Tornier B.V. Therefore the noncontrolling interest was accounted for in the consolidated financial statements as a contingently redeemable non-controlling interest that is initially recorded at fair value and classified as mezzanine equity.

However, pursuant to authoritative guidance, if the fair value of the contingently redeemable non-controlling interest is less than the current redemption value, and it is probable that the contingency related to the put option will be met, then the carrying value of the contingently redeemable non-controlling interest must be adjusted to its redemption value through a charge directly to equity. The Company has recognized \$0.7 million, \$1.1 million and \$3.8 million in accretion charges in 2010, 2009 and 2008 respectively, to reflect the contingently redeemable non-controlling interest at its current redemption value as it is probable the \$5 million sales contingency included in the put option will be met.

In accordance with authoritative guidance, the Company recorded the identifiable assets, liabilities and non-controlling interests in the VIE at their fair value upon initial consolidation. The C2M entity did not constitute a business at the time of consolidation and as a result the consolidation of C2M's related assets and liabilities were accounted for as the acquisition of an asset in accordance with applicable authoritative guidance. The primary asset consolidated consisted of the developed technology intangible asset underlying our Piton products. The fair value of this intangible asset was determined as of the date of consolidation based on the Company's consideration of a valuation performed using a discounted cash flow assessment together with consideration of historical transactions. The Company recognized \$0.7 million, \$1.1 million and \$1.2 million in net losses in 2010, 2009 and 2008, respectively,

Table of Contents**14. Non-Controlling Interests (Continued)**

as a result of the consolidation of C2M. These net losses consist primarily of intangible asset amortization and, as such, the results of consolidation of C2M did not have a significant impact on the consolidated cash flows of the Company. Total assets and liabilities of C2M are as follows (in thousands):

	January 2, 2011	December 27, 2009
Current assets	\$	\$ 697
Intangible asset, net	18,392	20,236
Deferred tax asset		621
Current liabilities		16
Contingent liabilities	1,860	3,167
Non-controlling interests		23,259

The intangible asset, net consists of developed technology. During 2010, the Company exercised its option to acquire the outstanding shares of C2M in exchange for Tornier ordinary shares. The transaction represents the acquisition of a non-controlling interest and as a result was accounted for as an equity transaction in accordance with ASC 810-10. Upon exercise of the purchase option, a non-controlling interest in C2M no longer existed. The balance of the non-controlling interest was eliminated and the fair value of the shares issued in the acquisition, \$23.2 million, was recorded as a component of shareholders' equity.

15. Certain Relationships and Related-Party Transactions

During 2009, the Company issued 185,697 shares pursuant to an agreement with a current shareholder based on the performance of an entity acquired in 2007.

The Company leases all of its approximately 55,000 square feet of manufacturing facilities and approximately 52,000 square feet of office space located in Grenoble, France, from the former Predecessor Company shareholder and current member of the board of directors. Annual lease payments to the member of the board of directors amounted to \$1.7 million, \$1.3 million and \$1.6 million during the years ended January 2, 2011, December 27, 2009 and December 28, 2008, respectively.

On July 29, 2008, the Company formed a real estate holding company (SCI Calyx) together with Mr. Tornier. SCI Calyx is owned 51% by the Company and 49% by Mr. Tornier. SCI Calyx was initially capitalized by a contribution of capital of €10,000 funded 51% by the Company and 49% by Mr. Tornier. SCI Calyx then acquired a combined manufacturing and office facility in Montbonnot, France, for approximately \$6.1 million. The manufacturing and office facility acquired will be used to support the manufacture of certain of the Company's current products and house certain operations already located in Montbonnot, France. This real estate purchase was funded through mortgage borrowings of \$4.1 million and \$2.0 million cash borrowed from the two current shareholders of SCI Calyx. The \$2.0 million cash borrowed from the SCI Calyx shareholders originally consisted of a \$1.0 million note due to Mr. Tornier and a \$1.0 million note due to Tornier SAS, which is the Company's wholly owned French operating subsidiary. Both of the notes issued by SCI Calyx bear interest at the three month Euribor rate plus 0.5% and have no stated term. During 2010, SCI Calyx borrowed approximately \$1.4 million from Mr. Tornier in order to fund on-going leasehold improvements necessary to prepare the Montbonnot facility for its intended use. This cash was borrowed under the same terms as the original notes. As of January 2, 2011, SCI Calyx had related-party debt outstanding to Mr. Tornier of \$2.4 million. The SCI Calyx entity is consolidated by the Company, and the related real estate and liabilities are included in the consolidated balance sheets. On

Table of Contents

15. Certain Relationships and Related-Party Transactions (Continued)

September 3, 2008, Tornier SAS, the Company's French operating subsidiary, entered into a lease agreement with SCI Calyx relating to these facilities. The agreement, which terminates in 2018, provides for an annual rent payment of €440,000, which has subsequently been increased and is currently €748,074 annually. As of January 2, 2011, future minimum payments under this lease were €5.7 million in the aggregate.

Since 2006, Tornier SAS has entered into various lease agreements with entities affiliated with Mr. Tornier or members of his family. On May 30, 2006, Tornier SAS entered into two lease agreements with Mr. Tornier and his sister, Colette Tornier, relating to our facilities in Saint-Ismier, France. The agreements provide for annual rent payments of €104,393 and €28,500, respectively, which have subsequently been increased and are currently €119,362 and €32,587 annually, respectively. On December 29, 2007, Tornier SAS entered into a lease agreement with Animus SCI, relating to our facilities in Montbonnot Saint Martin, France. The agreement provides for an annual rent payment of €252,545, which has subsequently been increased and is currently €288,756 annually. Animus SCI is wholly owned by Mr. Tornier. On December 29, 2007, Tornier SAS entered into a lease agreement with Cymaise SCI, relating to our facilities in Saint-Ismier, France. The agreement provides for an annual rent payment of €315,865, which has subsequently been increased and is currently €361,158 annually. Cymaise SCI is wholly owned by Mr. Tornier and his sister, Colette Tornier. On February 6, 2008, Tornier SAS entered into a lease agreement with Balux SCI, effective as of May 22, 2006, relating to our facilities in Montbonnot Saint Martin, France. The agreement provides for an annual rent payment of €480,000, which has subsequently been increased and is currently €548,828 annually. Balux SCI is wholly owned by Mr. Tornier and his sister, Colette Tornier. Each of the agreements will terminate in 2012. As of January 2, 2011, future minimum payments under these agreements were €1.9 million in the aggregate.

16. Other Non-Operating Expense

During the years ended January 2, 2011 and December 27, 2009, the Company recognized \$0.4 million of non-operating gain and \$28.0 million of non-operating expense primarily related to the mark-to-market of the warrant liability.

During the year ended December 28, 2008, the Company recognized \$1.4 million of non-operating expense related to the disposal of certain non-operating assets acquired in its Axya operations.

17. Special Charges

During the year ended December 27, 2009, the Company consolidated its U.S. operations and closed quality and regulatory sales and marketing functions in San Diego, California. Additionally, manufacturing operations in Beverly, Massachusetts, were also closed. Additionally, the Company opened sales offices in Scandinavia and the United Kingdom in 2009. The Company incurred \$1.9 million in costs related to the consolidation and launching of the sales sites. The operating costs for Scandinavia and the United Kingdom are included in sales and marketing expense. Included in the \$1.9 million of special charges are expenses incurred related to severance, lease termination, and moving costs related to consolidation of the Company's U.S. operations, as well as expenses for travel, consulting, and legal costs incurred to launch the sales sites. All expenses were paid in 2009.

During 2010, the Company recorded \$0.3 million in special charges related to commissions paid in the United Kingdom related to the termination of the relationship with a former distributor and expenses related to the Company's consolidation of its U.S. operations.

Table of Contents

18. Litigation

On October 25, 2007, two of our former sales agents filed a complaint in the U.S. District Court for the Southern District of Illinois, alleging that we had breached their agency agreements and committed fraudulent and negligent misrepresentations. The plaintiffs, Garry Boyd of Boyd Medical, Inc. and Charles Wetherill of Addison Medical, Inc., claimed that we had intentionally set their 2007 quotas too high, in hopes that Messrs. Boyd and Wetherill would not meet the quotas so that we could terminate them for cause and install another distributor in their territories. The complaint also included allegations that we had falsely suggested to the plaintiffs that if they dropped all other product lines, we would fill the void with new product lines. The jury rendered a verdict on July 31, 2009, awarding the plaintiffs a total of \$2.6 million in actual damages and \$4 million in punitive damages. While the court struck the award of punitive damages on March 31, 2010, it denied our motion to set aside the verdict or order a new trial. We have filed a notice of appeal with the U.S. Court of Appeals for the Seventh Circuit in respect of the remaining actual damages.

On July 7, 2010, the Company submitted its opening brief to the United States Court of Appeals for the Seventh Circuit. The Plaintiffs filed their opening briefs during August 2010. The consolidated appeal has been argued before the U.S. Court of Appeals for the Seventh Circuit. We expect a decision in the first half of 2011.

The Company has considered the facts of the case and related case law and, based on this information, we believe that the verdict rendered on July 31, 2009 was inappropriate given the related facts and supporting legal arguments. We have been successful in striking the jury awarded punitive damages through a motion filed with the original court. We have filed a notice of appeal with the U.S. Court of Appeals for the Seventh Circuit in respect of the remaining actual damages. We have considered the progress of the case, the views of legal counsel and the facts and arguments presented at the original jury trial and the fact that we intend to vigorously defend our position through the appellate courts in assessing the probability of a loss occurring for this matter. We believe we must assess the probability of the incurrence of a loss, and the ability to reasonably estimate such loss, based on the possible outcomes of the entire legal process including the appeals process. We believe our legal appeal is strong and that the range of possible outcomes is between zero and \$6.6 million. After assessing all relevant information, we do not believe there to be a reasonably estimable loss within the range of possible outcomes that is probable of occurring. As a result, we have not recorded an accrual for any loss related to this issue. We have determined that a loss is reasonably possible, and management estimates the range of loss to be between zero and \$6.6 million, the amount of the initial jury verdict. We believe we have a strong defense against these claims and are vigorously contesting these allegations. As of January 2, 2011, no accrual was recorded relating to this case.

In addition to the item noted above, we are subject to various other legal proceedings, product liability claims and other matters which arise in the ordinary course of business. In the opinion of management, the amount of liability, if any, with respect to these matters will not materially affect our consolidated results of operations or financial position.

19. Selected Quarterly Information (unaudited):

The following table presents a summary of our unaudited quarterly operating results for each of the four quarters in 2010 and 2009, respectively (in thousands). This information was derived from unaudited interim financial statements that, in the opinion of management, have been prepared on a basis consistent with the financial statements contained elsewhere in this filing and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such

Table of Contents**19. Selected Quarterly Information (unaudited): (Continued)**

information when read in conjunction with our audited financial statements and related notes. The operating results for any quarter are not necessarily indicative of results for any future period.

	Year-ended January 2, 2011			
	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
(in thousands, except per share data)				
Revenue	\$ 61,265	\$ 49,707	\$ 54,563	\$ 61,843
Gross profit	43,382	36,154	39,838	44,567
Consolidated net loss	(8,096)	(12,759)	(8,603)	(10,051)
Net loss attributable to ordinary shareholders	(8,096)	(12,759)	(8,603)	(10,035)
Net loss per share:				
basic and diluted	\$ (0.27)	\$ (0.43)	\$ (0.31)	\$ (0.41)

	Year-ended December 27, 2009			
	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
(in thousands, except per share data)				
Revenue	\$ 57,321	\$ 44,082	\$ 49,204	\$ 50,855
Gross profit	41,493	32,628	35,849	36,633
Consolidated net loss	(30,691)	(11,254)	(10,224)	(3,517)
Net loss attributable to ordinary shareholders	(30,750)	(11,255)	(10,224)	(3,517)
Net loss per share:				
Basic and diluted	\$ (1.25)	\$ (0.46)	\$ (0.42)	\$ (0.15)

The first quarter of the year-ended January 2, 2011 includes an additional week of operations relative to the first quarter of the year-ended December 27, 2009.

20. Subsequent Events (unaudited)

On January 28, 2011, the Company executed a 3-to-1 reverse stock split of the Company's ordinary shares. The consolidated financial statements as of January 2, 2011, December 27, 2009 and December 28, 2008 and for the years ended January 2, 2011, December 27, 2009 and December 28, 2008 give retroactive effect to the reverse stock split.

On January 28, 2011, the Company made a change to its legal form by converting from Tornier B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to Tornier N.V., a public company with limited liability (*naamloze vennootschap*).

In February 2011 the Company completed an initial public offering of 8,750,000 ordinary shares at an offering price of \$19.00 per share (before underwriters' discounts and commissions). The Company received proceeds of approximately \$155.4 million (after underwriters' discounts and commissions of approximately \$10.8 million, but before additional offering related costs). Net proceeds will be used for the retirement of debt, working capital, and other general corporate purposes. Additionally, on March 7, 2011, the Company issued an additional 721,274 ordinary shares at an offering price of \$19.00 per share (before underwriters' discounts and commissions) due to the exercise of the underwriters' overallotment option. The Company received proceeds of approximately \$12.8 million (after underwriters' discounts and commissions of approximately \$0.9 million.)

In February 2011, we used approximately \$116.1 million of the net proceeds from our initial public offering to repay all of the outstanding indebtedness under our notes payable, including accrued interest thereon, payable of approximately €86.4 million. At the time of repayment, we recognized a loss on debt extinguishment of approximately \$29.5 million and related deferred tax benefit of \$7.5 million to recognize the remaining balance of unamortized discount on the notes, and to reverse the related deferred tax liability.

Table of Contents

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 240.13a-15(e) and 240.15d-15(e) promulgated under the Securities Exchange Act of 1934) as of January 2, 2011. Based on that review and evaluation, which included inquiries made to certain other employees of the Company, the Certifying Officers have concluded that, as of the end of the period covered by this annual report, the Company's disclosure controls and procedures, as designed and implemented, are effective in ensuring that information relating to the Company required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such information is accumulated and communicated to the Company's management, including the Certifying Officers, as appropriate to allow timely decisions regarding required disclosure.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

Except as discussed below, no changes in our internal control over financial reporting occurred during the quarter ended January 2, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In connection with the audit of the Company's financial statements for 2009, we identified a material weakness in our internal control over financial reporting relating to our audited financial statements for fiscal years 2007 and 2008. Management and our independent registered accounting firm had determined that internal controls over identifying, evaluating and documenting accounting analysis and conclusions over complex non-routine transactions, including related-party transactions, require strengthening. During the year ended January 2, 2011, the Company implemented the following measures which it believes have addressed the material weakness identified above:

introduced formal policies and procedures regarding related party transactions which are subject to oversight by both senior management and the audit committee;

strengthened the communication and collaboration among the various departments within the Company;

reconfigured roles and responsibilities within the finance and accounting team to ensure sufficient resources are available to address such matters; and

further enhanced procedures to help ensure that proper accounting for all material complex, non-routine and related party transactions were researched and reviewed in conjunction with recording the transactions.

Item 9B. Other Information.

Not applicable.

Table of Contents**PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

We have a one-tier board structure. Our board of directors consists of eight members. The following table sets forth, as of January 2, 2011, certain information concerning our directors, executive and other officers.

Name	Age	Position
Douglas W. Kohrs	53	President, Chief Executive Officer and Executive Director
Carmen L. Diersen	50	Global Chief Financial Officer
Robert J. Ball	38	Vice President, Global Research and Development
Ralph E. Barisano, Jr.	50	Vice President, Global Quality Assurance and Regulatory Affairs
Stéphan Epinette	40	Vice President, International Commercial Operations
James C. Harber	41	Vice President, Distal Extremities Global Business Strategy
Andrew E. Joiner	49	Vice President and General Manager, U.S. Commercial Operations
Kevin M. Klemz	49	Vice President, Chief Legal Officer and Secretary
James E. Kwan	52	Vice President, Global Supply Chain
Gregory Morrison	47	Global Vice President, Human Resources
Jamal D. Rushdy	39	Vice President, Global Business and Corporate Development
Sean D. Carney(1)(2)	42	Chairman, Non-executive Director
Richard B. Emmitt(3)	66	Non-executive Director
Pascal E.R. Girin	50	Non-executive Director
Kevin C. O'Boyle(3)	54	Non-executive Director
Alain Tornier	64	Non-executive Director
Richard F. Wallman(3)(2)	59	Non-executive Director
Elizabeth H. Weatherman(1)	51	Non-executive Director

- (1) Member of the compensation committee.
- (2) Member of the nominating and corporate governance committee.
- (3) Member of the audit committee.

The following is a biographical summary of the experience of our directors, executive and other officers:

Douglas W. Kohrs was appointed as our President, Chief Executive Officer and a director in July 2006. Mr. Kohrs was appointed as a director in connection with the Securityholders' Agreement that we entered into with certain holders of our securities. For more information regarding the Securityholders' Agreement, please refer to the discussion below under "Related Party Transactions." Mr. Kohrs has 29 years of experience in the medical device industry. Prior to joining us he served as President and Chief Executive Officer of American Medical Systems Holdings, Inc., a publicly held medical device company, from April 1999 until January 2005 and served as Chairman of the American Medical Systems Holdings, Inc. board of directors until May 2006. During the past ten years, Mr. Kohrs has also served on the board of directors of nine different medical device companies. Mr. Kohrs previously served on the boards of ev3 Inc., a publicly held medical device company that was recently acquired by a wholly owned subsidiary of Covidien Group S.a.r.l., and Kyphon, Inc., a publicly held medical device company. Prior to joining American Medical Systems Holdings, Inc., Mr. Kohrs was General Manager of Sulzer Spine-Tech Inc., an orthopaedic implant manufacturer of which he was a founding member beginning in August 1991. Mr. Kohrs holds a Master of Business Administration from Northeastern University, a Bachelor of Science in Bioengineering from Texas A&M University and a Bachelor of Arts in Engineering Sciences from Austin College. Mr. Kohrs' prior experience, including as Chief

Table of Contents

Executive Officer of American Medical Systems Holdings, Inc. at the time of its initial public offering, and his understanding of our business and industry have led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Carmen L. Diersen joined us in June 2010 as Global Chief Financial Officer. She has 18 years of experience in the medical device industry, including nine years in spinal orthopaedics. Prior to joining us, she served from September 2006 to June 2010 as the Chief Operating and Financial Officer of Spine Wave, Inc., a privately held developer of advanced materials, techniques, and implant systems for spinal surgery. From March 2004 to September 2006, Ms. Diersen served as Executive Vice President and Chief Financial Officer of American Medical Systems Holdings, Inc., a publicly held medical device company. Prior to American Medical Systems Holdings, Inc., Ms. Diersen spent 12 years in financial leadership positions at Medtronic, Inc., in the cardiac surgery, cardiac rhythm management and spinal surgery businesses, concluding her career there as the Vice President and General Manager of Musculoskeletal Tissue Services for Medtronic Sofamor Danek. Prior to Medtronic, Inc., she spent 10 years at Honeywell, Inc. Ms. Diersen earned a Master of Business Administration from the Carlson School of Management at the University of Minnesota and a Bachelor of Science in Accounting from the University of North Dakota. She became a Certified Public Accountant in 1983. Ms. Diersen has served on the board of directors of SonoSite, Inc., a publicly held leader in point of care ultrasound systems, since October 2005 and previously served on the board of directors of Memry Corporation, a publicly held medical specialty materials company, from December 2004 through September 2008 when the company was sold and Wright Medical Group, Inc., a publicly held medical device company from December 2009 until June 2010 when she joined us.

Robert J. Ball joined us in September 2006 as Vice President, Global Research and Development. He has over 11 years of experience in the orthopaedic medical device industry. Prior to joining us he served as Vice President of Research Development of Kinetikos Medical Incorporated, or KMI, a medical device company, beginning in December 2002, and also assumed responsibility for Marketing and Product Development in May 2005, continuing in each capacity until August 2006, when KMI was acquired by Integra LifeSciences Holdings Corporation. Prior to joining KMI, Mr. Ball held positions at DePuy, where he oversaw the development and launch of orthopaedic products in the upper extremity. Prior to joining DePuy, he served in the automotive manufacturing industry with SPX Corporation as Program and Engineering Manager, overseeing construction and tooling of a large scale casting and machining facility. Mr. Ball has Bachelor of Science and Master of Science degrees in mechanical engineering from Kettering University (formerly GMI Engineering and Management Institute) and has over 30 issued and pending patents.

Ralph E. Barisano, Jr. joined us in April 2007 and leads our quality assurance and regulatory affairs programs as our Vice President, Global Quality Assurance and Regulatory Affairs. He has over 25 years of experience in the medical device industry. Prior to joining us he consulted for Axya, a medical device company, from November 2006 to April 2007, where he directed Quality Assurance and Regulatory Affairs including during its acquisition by us. Prior to joining Axya, he served as Director of Quality Assurance for Smith & Nephew Endoscopy, a manufacturer of surgical equipment and tools, from January 2002 to November 2006. Mr. Barisano has also held other Quality and Regulatory roles at a number of other medical device companies, including Hologic Systems Inc., C.R. Bard, Inc. and Allergan, Inc. Mr. Barisano earned a Master of Business Administration from the Isenberg School of Management, University of Massachusetts Amherst and a Bachelor of Science in Mechanical Engineering Technology from the University of Massachusetts, North Dartmouth.

Stéphan Epinette joined us in December 2008 and leads our international commercial operations (Europe, Asia Pacific, Latin America) and large joints business as Vice President of International Commercial Operations. He has over 17 years of experience in the orthopaedic medical device industry. Prior to joining us, he served in various leadership roles with Stryker Corporation, a medical device and equipment company, in its MedSurg and Orthopaedic divisions in France, the United States and Switzerland from 1993 to December 2008, including as Business Unit Director France from 2005 to

Table of Contents

2008. His past functions at Stryker Corporation also included Marketing Director MedSurg EMEA, Assistant to the EMEA President and Director of Business Development & Market Intelligence EMEA. Mr. Epinette earned a Masters Degree in Health Economics from Sciences Politiques, Paris, a Masters Degree in International Business from Paris University XII and a Bachelor of Arts from EBMS Barcelona. He also attended the INSEAD executive course in Finance and in Marketing.

James C. Harber joined us in February 2007 following our acquisition of Nexa and leads our distal extremities organization as our Vice President, Distal Extremities Global Business Strategy, which consists of our foot, ankle, hand, wrist, and elbow joints and trauma products. He has over 20 years of experience in the orthopaedic medical device industry. At Nexa, he served as the Vice President of Marketing and Sales from March 2006 until June 2007. Prior to joining Nexa, Mr. Harber held the position of Vice President, Marketing at Hand Innovations LLC, an orthopaedic manufacturer from August 2003 to February 2006. He has also held marketing positions at Wright Medical Group, Inc. and Smith & Nephew plc, which are both medical device companies, and was Vice President of Sales and Marketing at a development stage computer assisted surgery venture. Mr. Harber earned a Bachelor of Science in Marketing from Christian Brothers University.

Andrew E. Joiner joined us in April 2008 and leads our U.S. sales and marketing activities and the global shoulder business as our Vice President and General Manager, U.S. Commercial Operations. He has over 19 years of experience in the medical device industry. Prior to joining us, he served as the Vice President and General Manager of Women's Health at American Medical Systems Holdings, Inc. from January 2007 to April 2008, and as the Vice President of Global Marketing at American Medical Systems Holdings, Inc., from 2005 to December 2006. Prior to American Medical Systems Holdings, Inc., Mr. Joiner worked for ten years for United States Surgical Corporation, a surgical tools company, in a variety of sales functions, concluding his career there as Director of Sales for the Southwest Region of the U.S. Mr. Joiner holds a Bachelor of Science in Telecommunications from the University of Georgia.

Kevin M. Klemz joined us in September 2010 as Vice President, Chief Legal Officer and Secretary. Prior to joining us, Mr. Klemz served as Senior Vice President, Secretary and Chief Legal Officer at ev3 Inc. from August 2007 to August 2010, and as Vice President, Secretary and Chief Legal Officer at ev3 Inc. from January 2007 to August 2007. Prior to joining ev3 Inc., Mr. Klemz was a partner in the law firm Oppenheimer Wolff & Donnelly LLP, where he was a corporate lawyer for approximately 20 years. Mr. Klemz has a Bachelor of Arts in Business Administration from Hamline University and a Juris Doctor from William Mitchell College of Law.

James E. Kwan joined us in September 2006 and leads our global supply chain organization as our Vice President, Global Supply Chain. Mr. Kwan has also served as Director of Tornier Orthopaedics Ireland Ltd., one of our subsidiaries, since March 2010. He has over 20 years of experience in the medical device industry. Prior to joining us, he served as the Vice President of Operations for the Cardiac Surgery Division for St. Jude Medical, Inc., a medical technology company, from 2004 to 2006. At St. Jude Medical, Inc., Mr. Kwan also served as the Director of Hybrid Microelectronics operations for the Cardiac Rhythm Management Division and managed the Pyrolytic Carbon Technology operations for the Heart Valve Division. Prior to joining St. Jude Medical, Inc., Mr. Kwan served as a Director of Manufacturing at SciMed Life Systems, an interventional cardiology company, and before that held various technical positions within the Defense Systems Division of Honeywell International, Inc., a diversified technology company. Mr. Kwan received a Bachelor of Science in Mechanical Engineering from South Dakota School of Mines & Technology and a Master of Business Administration from the University of St. Thomas.

Gregory Morrison joined us in December 2010 as Global Vice President, Human Resources. Prior to joining us, Mr. Morrison served as Senior Vice President, Human Resources at ev3 Inc. from August 2007 to December 2010, and as Vice President, Human Resources from May 2002 to August 2007. Prior to joining ev3 Inc., Mr. Morrison served as Vice President of Organizational Effectiveness for

Table of Contents

Thomson Legal & Regulatory from March 1999 to February 2002 and Vice President of Global Human Resources for Schneider Worldwide (Boston Scientific) from 1988 to March 1999. Mr. Morrison has a Bachelor of Arts in English and Communications from North Adams State College and a Master of Arts in Corporate Communications from Fairfield University

Jamal D. Rushdy joined us in February 2007 when we acquired Nexa, a medical device company, and leads our corporate strategic planning and acquisition, licensing and partnership programs and our sports medicine and biologics businesses, serving as our Vice President, Global Business and Corporate Development since June 2007. He has over 15 years of experience in the orthopaedic medical device industry. At Nexa, he served from January 2006 to May 2007 as the Vice President of Operations and Business Development until its acquisition by us. Prior to Nexa, he served as Director of Marketing and Business Development for dj Orthopedics LLC, a medical device company, where he also served in various leadership roles in finance and operations from June 2001 to January 2006. Mr. Rushdy earned a Master of Business Administration from the University of California, Irvine and a Bachelor of Science in Mechanical Engineering from the University of California, San Diego.

Sean D. Carney is one of our directors and has served as a director since July 2006. Mr. Carney was appointed as a director in connection with the Securityholders' Agreement that we entered into with certain holders of our securities. Mr. Carney became the Chairman of the Company's board of directors in May 2010. For more information regarding the Securityholders' Agreement, please refer to the discussion below under "Related Party Transactions." Since 1996, Mr. Carney has been employed by Warburg Pincus LLC and has served as a Member and Managing Director of Warburg Pincus LLC and General Partner of Warburg Pincus & Co. since January 2001. Warburg Pincus LLC and Warburg Pincus & Co. are part of the Warburg Pincus entities collectively referred to elsewhere in this prospectus as Warburg Pincus, our stockholder that owns approximately 47% of our ordinary shares as of January 2, 2011. Mr. Carney formerly served on the board of directors of Arch Capital Group Ltd., a publicly held company. He is also a member of the board of directors of Bausch & Lomb Inc. and several other private companies. During the past five years, Mr. Carney previously served on the board of directors of DexCom, Inc., a publicly held medical device company. Mr. Carney received a Master of Business Administration from Harvard Business School and a Bachelor of Arts from Harvard College. Mr. Carney's substantial experience as an investor and director in medical device companies and his experience evaluating financial results have led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Richard B. Emmitt is one of our directors and has served as a director since July 2006. Mr. Emmitt was appointed as a director in connection with the Securityholders' Agreement that we entered into with certain holders of our securities. For more information regarding the Securityholders' Agreement, please refer to the discussion below under "Related Party Transactions." Mr. Emmitt served as a General Partner of The Vertical Group LP, an investment management and venture capital firm focused on the medical device and biotechnology industries, from its inception in 1989 through December 2007. Commencing in January 2008, he has been a Member and Manager of The Vertical Group GP, LLC, which controls The Vertical Group LP. Mr. Emmitt currently serves on the board of directors of American Medical Systems Holdings, Inc., a publicly held company, as well as several privately held companies. During the past five years, Mr. Emmitt previously served on the board of directors of Wright Medical Group, Inc. and Micro Therapeutics, Inc., all publicly held medical device companies and ev3 Inc. Mr. Emmitt holds a Master of Business Administration from the Rutgers School of Business and a Bachelor of Arts from Bucknell University. Mr. Emmitt's substantial experience as an advisor to numerous venture-backed growth companies and as an advisor to high-growth companies has led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Pascal E.R. Girin is one of our directors and has served as a director since November 2010. Mr. Girin was appointed as a director in connection with the Securityholders' Agreement that we entered into with certain holders of our securities. For more information regarding the Securityholders'

Table of Contents

Agreement, please refer to the discussion below under "Related Party Transactions." Since February of 2011, Mr. Girin has served as President and Chief Executive Officer of Keystone Dental Inc. Prior to that, from October 2010 to February 2011, Mr. Girin served as Executive Vice President and Chief Operating Officer of Keystone Dental Inc. From July 2010 to September 2010, Mr. Girin served as Chief Operating Officer of ev3 Inc. following its acquisition by a wholly owned subsidiary of Covidien Group S.a.r.l. Prior to that time, Mr. Girin served as Executive Vice President and Chief Operating Officer of ev3 Inc. from January 2010 to July 2010, as Executive Vice President and President, Worldwide Neurovascular and International of ev3 Neurovascular Inc. from July 2008 to January 2010, as Senior Vice President and President, International of ev3 International from July 2005 to July 2008, and as General Manager, Europe of ev3 Inc. from September 2003 to July 2005. From September 1998 to August 2003, Mr. Girin served in various capacities at BioScience Europe Baxter Healthcare Corporation, most recently as Vice President. Mr. Girin received an Engineering Education at the French Ecole des Mines. Mr. Girin's substantial experience as an executive at other global medical device companies has led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Kevin C. O'Boyle is one of our directors and has served as a director since June 2010. Since December of 2010, Mr. O'Boyle has served as Senior Vice President and Chief Financial Officer of Advanced BioHealing Inc., a medical device company. From January 2003 until December 2009, Mr. O'Boyle served as the Chief Financial Officer of NuVasive, Inc., a medical device company that completed its initial public offering in May 2004. Prior to that time, Mr. O'Boyle served in various positions during his six years with ChromaVision Medical Systems, Inc., a publicly held medical device company specializing in the oncology market, including as its Chief Financial Officer and Chief Operating Officer. Mr. O'Boyle also held various positions during his seven years with Albert Fisher North America, Inc., a publicly held international food company, including Chief Financial Officer and Senior Vice President of Operations. He currently serves on the board of GenMark Diagnostics, Inc., a publicly traded molecular diagnostics company. Mr. O'Boyle is a Certified Public Accountant and received a Bachelor of Science in Accounting from the Rochester Institute of Technology and successfully completed the Executive Management Program at the University of California Los Angeles, John E. Anderson Graduate Business School. Mr. O'Boyle's executive experience in the healthcare industry, his experience with companies during their transition from a privately held to a public company and his financial and accounting expertise have led our board of directors to the conclusion that Mr. O'Boyle should serve as a director and on our audit committee at this time in light of our business and structure.

Alain Tornier is one of our directors and has served as a director since May 1976. Mr. Tornier assumed a leadership role in our predecessor entity in 1976, following the death of his father, René Tornier, our founder. He later served as our President and Chief Executive Officer until our acquisition by the Investor Group in September 2006, when he retired. Mr. Tornier holds a Master of Sciences degree from Grenoble University. Mr. Tornier's significant experience in the global orthopaedics industry and deep understanding of our company's history and operations have led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Richard F. Wallman is one of our directors and has served as a director since December 2008. From 1995 through his retirement in 2003, Mr. Wallman served as the Senior Vice President and Chief Financial Officer of Honeywell International, Inc., a diversified technology company, and AlliedSignal, Inc., a diversified technology company (prior to its merger with Honeywell International, Inc.). Prior to joining AlliedSignal, Inc. as Chief Financial Officer, Mr. Wallman served as Controller of International Business Machines Corporation. In addition to serving as one of our directors, he is also a member of the board of directors of Ariba, Inc., Charles River Laboratories International, Inc., Convergys Corporation, Dana Holding Corporation, and Roper Industries, Inc., all publicly held companies. He is also a member of the board of directors of Bausch & Lomb Inc. During

Table of Contents

the past five years, Mr. Wallman previously served on the board of directors of ExpressJet Holdings Inc. and Avaya Inc., as well as auto suppliers Lear Corporation and Hayes Lemmerz International, Inc., all publicly held companies. Mr. Wallman holds a Master of Business Administration from the University of Chicago Booth School of Business with concentrations in finance and accounting and a Bachelor of Science in Electrical Engineering from Vanderbilt University. Mr. Wallman's prior public company experience, including as Chief Financial Officer of Honeywell, and his financial experience and expertise, have led our board of directors to the conclusion that he should serve as a director at this time in light of our business and structure.

Elizabeth H. Weatherman is one of our directors and has served as a director since July 2006. Ms. Weatherman was appointed as a director in connection with the Securityholders' Agreement that we entered into with certain holders of our securities. For more information regarding the Securityholders' Agreement, please refer to the discussion below under "Related Party Transactions." Ms. Weatherman is a General Partner of Warburg Pincus & Co., a Managing Director of Warburg Pincus LLC and a member of the firm's Executive Management Group. Ms. Weatherman joined Warburg Pincus in 1988 and is currently responsible for the firm's U.S. healthcare investment activities. Warburg Pincus LLC and Warburg Pincus & Co. are part of the Warburg Pincus entities collectively referred to elsewhere in this prospectus as Warburg Pincus, our stockholder that owns approximately 47% of our ordinary shares as of January 2, 2011. Ms. Weatherman currently serves on the board of directors of Bausch & Lomb Inc. and several other privately held companies. During the past five years, Ms. Weatherman previously served on the board of directors of American Medical Systems Holdings, Inc., Kyphon, Inc., Micro Therapeutics, Inc., and Wright Medical Group, Inc., all publicly held companies, and ev3 Inc. Ms. Weatherman earned a Master of Business Administration from the Stanford Graduate School of Business and a Bachelor of Arts from Mount Holyoke College. Ms. Weatherman's extensive experience as a director of public companies in the medical device industry has led our board of directors to the conclusion that she should serve as a director at this time in light of our business and structure.

Board of Directors

Our board of directors currently consists of eight directors, seven of whom are non-executive directors. The Chief Executive Officer is the executive director. All of our non-executive directors, except Mr. Tornier, are independent under the independence criteria of NASDAQ. Therefore, six of the eight directors are independent. Independence requirements for service on the audit committee is discussed below under "Committees of the Board of Directors Audit Committee." Mr. Wallman and Mr. O'Boyle are independent under the independence definition in the Dutch Corporate Governance Code. Because we currently comply with the NASDAQ corporate governance requirements, the Dutch Corporate Governance Code requirement that a majority of our directors be independent does not apply provided we explain such deviation in our annual report.

Our amended articles of association provide that the number of members of the board of directors will be determined by the board of directors, provided that at all times the board of directors shall be comprised of at least one executive director and two non-executive directors. Our board of directors and our shareholders have each approved that our board of directors be divided into three classes, as nearly equal in number as possible, with each director serving a three-year term and one class being elected at each year's annual meeting of shareholders. Alain Tornier, Pascal E.R. Girin and Elizabeth H. Weatherman are in the class of directors whose term expires at the 2011 annual general meeting of our shareholders. Sean D. Carney, Douglas W. Kohrs and Richard B. Emmitt are in the class of directors whose term expires at the 2012 annual meeting of our shareholders. Richard F. Wallman and Kevin C. O'Boyle are in the class of directors whose term expires at the 2013 annual meeting of our shareholders. At each annual meeting of our shareholders, successors to the class of directors whose term expires at such meeting will be elected to serve for three-year terms or until their respective successors are elected and qualified.

Table of Contents

The general meeting appoints the members of the board of directors, subject to a binding nomination of the board of directors in accordance with the relevant provisions of the Dutch Civil Code. The board of directors will make the binding nomination based on a recommendation of the Nominating and Corporate Governance Committee. A nominee is deemed appointed unless the general meeting opposes the use of the binding nomination procedure by a resolution passed with the affirmative vote of at least two-thirds majority of the votes cast, which votes also represent more than 50% of our issued share capital. In such case, a new meeting is called to fill the vacancies for which the binding nominations were initially made. Nominees for appointment are presented by the board of directors. These nominations are not binding. The resolution for appointment in such meeting shall require the affirmative vote of at least two-thirds majority of the votes cast representing more than 50% of our issued share capital.

If the board of directors fails to use its right to submit a binding nomination, the general meeting may appoint members of the board of directors with a resolution passed with the affirmative vote of at least a two-thirds majority of the votes cast, representing more than 50% of our issued share capital. A resolution of the general meeting to suspend a member of the board of directors requires the affirmative vote of an absolute majority of the votes cast. A resolution of the general meeting to suspend or dismiss members of the board of directors, other than pursuant to a proposal by the board of directors, requires a majority of at least two-thirds of the votes cast, representing more than 50% of our issued share capital.

Pursuant to the Securityholders' Agreement, dated July 18, 2006, by and among Tornier N.V., formerly known as TMG B.V., TMG, TMG Partners U.S. LLC, Mr. Kohrs, VFI, VFII, KCH, Mr. Tornier, WP Bermuda and (by subsequent joinder agreements) TMG Partners II LLC, TMG Partners III LLC, Split Rock Partners, L.P., or Split Rock, Stichting Administratiekantoor Tornier, or STAK, Medtronic Bakken Research Center B.V., or Medtronic, and DVO TH, L.L.C., or DVO TH, as amended on August 27, 2010, TMG has 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 the Company has agreed to use its reasonable best efforts to cause the TMG designees to be elected. In addition, Mr. Kohrs will continue to be entitled to be nominated for election to the board of directors until termination of his employment.

No family relationships exist among any of our directors, executive officers or key employees.

Under our amended articles of association, the internal rules for the board of directors and the board committees and Dutch law, the members of the board of directors are collectively responsible for the management, general and financial affairs and policy and strategy of our company.

The executive director is our Chief Executive Officer, who is primarily responsible for managing our day-to-day affairs as well as other responsibilities that have been delegated to the executive director in accordance with our amended articles of association and our internal rules for the board of directors. The non-executive directors supervise the Chief Executive Officer and our general affairs and provide general advice to our Chief Executive Officer. In performing their duties, the non-executive directors are guided by the interests of the Company and shall, within the boundaries set by relevant Dutch law, take into account the relevant interests of our stakeholders. The internal affairs of the board of directors are governed by our rules for the board of directors.

Table of Contents

It is expected that all meetings of the board of directors will be held in the Netherlands. Each director has the right to cast one vote and may be represented at a meeting of the board of directors by a fellow director. The board of directors may pass resolutions only if a majority of the directors is present at the meeting and all resolutions must be passed by a majority of the directors present or represented. However, as required by Dutch law, our amended articles of association provides that when one or more members of the board of directors is absent or prevented from acting, the remaining members of the board of directors will be entrusted with the management of our company. The intent of this provision is to satisfy certain requirements under Dutch law and provide that, in rare circumstances, when a director is incapacitated, severely ill or similarly absent or prevented from acting, the remaining members of the board (or, in the event there are no such remaining members, a person appointed by our shareholders at a general meeting) will be entitled to act on behalf of the board in the management of our company, notwithstanding the general requirement that otherwise requires a majority of our board be present. In these limited circumstances, our amended articles of association permit our board of directors to pass resolutions even if a majority of the directors is not present at the meeting.

Subject to Dutch law and any director's objection, resolutions may be passed in writing by a majority of the directors in office. Pursuant to the internal rules for our board of directors, a director may not participate in discussions or the decision-making process on a transaction or subject in relation to which he or she has a conflict of interest with us. Resolutions to enter into such transactions must be approved by a majority of our board of directors, excluding such interested director or directors.

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below.

Audit Committee. Our audit committee oversees a broad range of issues surrounding our accounting and financial reporting processes and audits of our financial statements. Our audit committee (i) assists our board of directors in monitoring the integrity of our financial statements, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence and the performance of our internal audit function and independent auditors; (ii) assumes direct responsibility for the appointment, compensation, retention and oversight of the work of any independent registered public accounting firm engaged for the purpose of performing any audit, review or attest services and for dealing directly with any such accounting firm; and (iii) provides a medium for consideration of matters relating to any audit issues.

Our audit committee consists of Mr. Wallman (Chair), Mr. Emmitt and Mr. O'Boyle. We believe that the composition of our audit committee complies with the applicable rules of the SEC and the NASDAQ Global Select Market. The board of directors has determined that Mr. Wallman, Mr. Emmitt and Mr. O'Boyle are each an "audit committee financial expert," as defined in the SEC rules, and satisfy the financial sophistication requirements of the NASDAQ Global Select Market. Messrs. Wallman, Emmitt and O'Boyle are independent as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and the rules of the NASDAQ Global Select Market. Messrs. Wallman and O'Boyle are independent as such term is defined under the Dutch Corporate Governance Code.

Our board of directors has adopted a written charter for the audit committee, which is available on our website.

Compensation Committee. Within the scope of the compensation policy adopted by the general meeting, our compensation committee reviews and recommends policy relating to compensation for and benefits of our officers and employees, including reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other senior officers,

Table of Contents

evaluating the performance of these officers in light of those goals and objectives and setting compensation of these officers based on such evaluations. The compensation committee reviews and evaluates, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter. Our compensation committee has sole discretion concerning the administration of our option plans, including the selection of individuals to receive awards and the time at which awards will be granted.

None of our executive officers have served as a member of the board of directors or compensation committee of any entity that has an executive officer serving as a member of our board of directors.

Our compensation committee and board of directors has reviewed and discussed the Compensation Discussion and Analysis with the Company's management. Based on this review and these discussions, the board of directors recommended that the Compensation Discussion and Analysis be included in the Company's annual report on Form 10-K.

Sean D. Carney
Elizabeth H. Weatherman

Our compensation committee consists of Mr. Carney (Chair) and Ms. Weatherman. Our board of directors has adopted a written charter for the compensation committee that is available on our website.

Nominating and Corporate Governance Committee. The nominating and corporate governance committee oversees and assists our board of directors in identifying, reviewing and recommending nominees for election as directors; evaluate our board of directors and our management; develops, reviews and recommends corporate governance guidelines and a corporate code of business conduct and ethics; and generally advises our board of directors on corporate governance and related matters.

Our nominating and corporate governance committee consists of Mr. Carney (Chair) and Mr. Wallman. Our board of directors has adopted a written charter for the nominating and corporate governance committee, a copy of which is available on our website.

The nominating and corporate governance committee considers all candidates recommended by our shareholders pursuant to those specific minimum qualifications that the nominating and corporate governance committee believes must be met by a recommended nominee for a position on the Company's board of directors as described in the above referenced written charter of the nominating corporate governance committee.

Our board of directors may from time to time establish other committees.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, which applies to all of our directors, officers, and employees. Our Code of Business Conduct and Ethics is available on our website free of charge at www.tornier.com, under Corporate Governance. Any person may request a copy free of charge by writing to us at Tornier, Inc., 7701 France Avenue South, Suite 600, Edina, Minnesota 55435. We intend to disclose on our website any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics that applies to directors and executive officers and that is required to be disclosed pursuant to the rules of the SEC.

Section 16(a) Beneficial Ownership Reporting Compliance

We did not become subject to the Exchange Act during the fiscal year ending January 2, 2011, and therefore no officers, directors or shareholders who hold greater than 10% of our ordinary shares were required to file Section 16(a) reports of ownership and reports of changes in ownership of our ordinary shares and other of our equity securities in relation to the Company.

Table of Contents

Item 11. Executive Compensation.

Our "named executive officers" for 2010 consisted of the following individuals:

Douglas W. Kohrs, who currently serves as our President, Chief Executive Officer and Director;

Michael J. Doty, who served as our Global Chief Financial Officer until February 19, 2010;

Carmen L. Diersen, who currently serves as our Global Chief Financial Officer;

Andrew E. Joiner, who currently serves as our Vice President and General Manager, U.S. Commercial Operations;

Kevin M. Klemz, who currently serves as our Vice President, Chief Legal Officer and Secretary; and

Stéphan Epinette, who currently serves as our Vice President, International Commercial Operations.

Compensation Overview and Objectives

Because we were a private company prior to February 2011, compensation decisions with respect to our named executive officers have generally been based on the goal of achieving performance at levels necessary to provide meaningful returns to our shareholders upon an ultimate liquidity event. To that end, in addition to the typical need to attract, motivate and retain talented executives, our compensation programs in 2010 were specifically designed to incentivize our named executive officers to achieve short- and long-term performance goals that would enable us to substantially increase our equity value and make us an attractive candidate for either a public offering of our ordinary shares or a sale, and to provide our named executive officers with meaningful compensation upon the occurrence of such an event. Our compensation programs in 2010 were weighted toward performance-based compensation, including equity-based compensation, such that our named executive officers will see returns primarily based upon the returns achieved by our shareholders. In 2010, we modified our annual bonus program for our named executive officers to be weighted 80% on the achievement of corporate performance goals and 20% on the achievement of individual goals.

Determination of Compensation

For services performed for us and our subsidiaries during 2010, our named executive officers were generally compensated by the operating subsidiary to which such named executive officer primarily provided services. Our board of directors was ultimately responsible for determining our compensation and benefit plans generally, and established and reviewed all compensatory plans and arrangements with respect to our named executive officers. The board of directors meets not less than annually to specifically review and determine adjustments, if any, to all elements of compensation, including base salary, annual bonus compensation and long-term equity awards, including to evaluate the achievement of performance goals for the prior fiscal year and to set new performance goals for the current fiscal year. The board of directors also met periodically to discuss compensation-related matters as they arose during the year. In addition, with respect to the compensation of our named executive officers, other than our Chief Executive Officer, the board of directors sought the input and recommendation of our Chief Executive Officer. Our Chief Executive Officer reviewed each other named executive officer's overall performance and contribution to the Company at the end of each fiscal year and made recommendations regarding each element of their compensation to Mr. Carney, one of our directors, who then consulted informally with our Chief Executive Officer regarding his recommendations and in turn presented his recommendations to our full board of directors for final determinations. Our Chief Executive Officer's compensation was determined based on recommendations made by Mr. Carney to the full board of directors. Our Chief Executive Officer did not participate in any formal discussion

Table of Contents

with the board of directors regarding his compensation decisions and he recused himself from meetings when his compensation was discussed.

The board of directors did not generally rely on formulaic guidelines for determining the mix or levels of cash and equity-based compensation, but rather maintained a flexible compensation program that allowed it to adapt components and levels of compensation to motivate and reward individual executives within the context of our desire to attain certain strategic and financial goals. Subjective factors considered in compensation determinations include an executive's skills and capabilities, contributions as a member of the executive management team, contributions to our overall performance and the sufficiency of total compensation potential and structure to ensure the retention of an executive when considering the compensation potential that may be available elsewhere.

In making its determination, the board of directors did not undertake any formal benchmarking or reviewed any surveys commissioned by us of compensation for our competitors, but instead relied primarily on its members' general knowledge of the competitive market.

Components of Compensation for 2010

For 2010, the compensation provided to our named executive officers consisted of base salary, annual bonus, long-term equity-based compensation, retirement benefits and other perquisites and benefits, each of which is described in more detail below. We believe that the mix of cash- and equity-based compensation, as well as the relationship of fixed to performance-based compensation, is properly balanced and provides us with an effective means to attract, motivate and retain our named executives, as well as reward them for creation of shareholder value.

Base Salary

The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salary amounts are established under each named executive officer's employment agreement, but are subject to upward adjustment by the board of directors based on its consideration of, among other factors, the scope of the executive's responsibilities, individual performance for the prior year, the mix of fixed compensation to overall compensation and consistency with what the board of directors and our Chief Executive Officer consider to be the market standard for compensation paid to similarly-situated executives at other companies. Initially, base salary was determined at the time of a named executive officer's hire, based on the above elements at such time, and such initial amount forms the basis for base salary throughout a named executive officer's tenure with the Company, with adjustments being made by the board of directors as and when appropriate, based on changes in the above elements over time and consistent with our compensation objectives. Base salary amounts for Ms. Diersen and Mr. Klemz were determined at their time of hire by our board of directors and our Chief Executive Officer, based on their consideration of factors such as the scope of Ms. Diersen's and Mr. Klemz's roles and responsibilities, our overall compensation program, and market standards for compensation paid to similarly-situated executives at other companies based on their general knowledge of the competitive market. In 2010, our board of directors established a Company-wide guideline that provided for an average salary increase for all employees, other than employees in performance review, of an approximate cost of living adjustment of 3% of 2009 salary, with the actual amount of any employee's raise determined based on 2009 performance. In 2010, Mr. Kohrs received a 3% raise and Mr. Epinette received a 4% raise pursuant to these guidelines and based on the board's subjective evaluation of their performance. Mr. Joiner's base salary was increased by 8.3% in 2010 to reward him for his service based on the board's subjective evaluation of his performance as to the performance factors described above and to keep his base salary in line with what the board of directors and our Chief Executive Officer determined was the market standard for compensation paid to similarly-situated executives at other companies based on their general knowledge of the competitive market.

Table of Contents**Annual Bonuses**

Annual bonuses are intended to compensate executives for achieving annual Company-wide financial goals and individual performance goals. Target bonus amounts (60% of base salary for Mr. Kohrs, 50% of base salary for Mr. Joiner, 50% of base salary for Ms. Diersen, 40% of base salary for Mr. Klemz and 30% of base salary for Mr. Epinette) were established under each named executive officer's employment agreement at the time such agreements were entered into, with actual bonuses for a given fiscal year being based upon the achievement of the applicable performance objectives. Target bonus amounts for Ms. Diersen and Mr. Klemz were determined by our board of directors and our Chief Executive Officer based on their consideration of our overall compensation program and market standards for compensation paid to similarly-situated executives at other companies based on their general knowledge of the competitive market. The 2010 target bonus percentages for the other named executive officers did not change from their 2009 levels. For 2010, the payment of annual bonuses to our named executive officers was based 80% upon achievement of corporate performance goals relating to our revenue, Modified EBITDA, revenue over net inventories plus gross instruments, cash flows, and year-end days sales outstanding, and 20% upon the named executive officer's achievement of individual performance goals described below. For 2010, Ms. Diersen and Mr. Klemz received pro-rated annual bonuses based on the number of days they were employed by the Company in 2010.

The following table sets forth the financial performance criteria for the 2010 bonus program which were established by the board of directors on March 3, 2010, the range of possible payouts and the actual payout percentage for named executive officers based on the performance achieved. At their respective times of hire, our board of directors and our Chief Executive Officer determined that the portion of Ms. Diersen's and Mr. Klemz's 2010 pro-rated annual bonuses tied to corporate performance goals should be based upon achievement of the same financial performance criteria applicable to our other named executive officers' 2010 annual bonuses, in order to encourage consistent behavior among our named executive officers and to promote the achievement of overall corporate performance goals.

If performance achieved falls between the threshold, target and maximum levels, actual payout percentages are determined on a sliding scale basis, with payouts starting at 50% of target for minimum performance achievement and capped at 150% of target for maximum achievement. For 2010, the total weighted-average payout percentage applicable to the portion of the 2010 annual bonus tied to objective performance goals was 78.7%, as detailed in the table below. The compensation committee approved payouts at this percentage for the portion of the named executive officers' bonuses tied to corporate performance goals.

Modified metrics(2)	Weight (% of 2010 bonus tied to performance of this metric)	Performance targets(1)			Payout percentage			2010 Performance (\$)	Level of 2010 payout
		Threshold	Target	Maximum	Threshold	Target	Maximum		
Modified Revenue	32%	\$215.1 million	\$239.0 million	\$282.0 million	50%	100%	150%	234.9 million	91%
Modified EBITDA(3)	28%	\$17.7 million	\$19.7 million	\$25.4 million	50%	100%	150%	18.6 million	74%
Modified Revenue/(Net Inventories + Gross Instruments)(4)	8%	1.38	1.53	1.80	50%	100%	150%	1.55	101%
Modified Cash From Operations(5)	8%	\$(18.9) million	\$(17.2) million	\$(11.8) million	50%	100%	150%	(21.2) million	77%
Modified Days Sales Outstanding (Year-End)(6)	4%	78.0	70.9	60.3	50%	100%	150%	67.1	105%

(1) The performance targets were established based on an assumed foreign currency exchange rate of 1.45 U.S. dollars for 1 Euro, which represented an anticipated average rate of foreign exchange for 2010 and which was the rate of foreign exchange used by the Company for 2010 budgeting purposes.

(2) The compensation committee determined 2010 bonus amounts after reviewing our unaudited financial statements for the 2010 fiscal year, which are adjusted for changes to the foreign exchange rates and which are subject to discretionary adjustment by the board for items that

Table of Contents

are unusual and not reflective of normal operations. For purposes of determining 2010 bonus amounts, in addition to foreign exchange adjustments, the board made additional adjustments discussed in the footnotes below. Accordingly, the figures included in the "2010 Performance" column reflect foreign exchange rate and discretionary board adjustments and differ from the figures reported in our 2010 audited financial statements.

- (3) "Modified EBITDA" means our earnings before interest, taxes, depreciation and amortization.
- (4) "Modified Revenue/(Net Inventories + Gross Instruments)" means our annual revenue divided by the annual average of the sum of net inventories and gross instruments before accumulated depreciation. Gross instruments refers to the acquisition cost of the fixed assets.
- (5) "Modified Cash from Operations" means our cash generated by (used in) operations, reduced by capital expenditures and instrument expenditures, adjusted as described in footnote (2) to be further reduced by deferred financial costs in the amount of \$3.5 million.
- (6) "Modified Days Sales Outstanding (Year-End)" is a measure of the average number of days of revenue included in the net accounts receivable reported on the balance sheet at year end.

Individual performance goals for 2010 were communicated to each of our named executive officers, other than Mr. Klemz and Ms. Diersen, by our Chief Executive Officer (or, in the case of our Chief Executive Officer, our board of directors) at the beginning of 2010. Individual performance goals for 2010 for Mr. Klemz and Ms. Diersen were communicated to them by our Chief Executive Officer at their respective times of hire. These individual performance goals were primarily based on the named executive officer's ability to interact with peers, performance of the named executive officer's direct reports (including the success in recruiting top level talent), development and strengthening of the named executive officer's relationships with our vendors, distributors and customers, and overall contribution to the Company. The portion of the 2010 annual bonus tied to individual performance goals is capped at 100% of target for maximum achievement. For 2010, the compensation committee considered Mr. Kohrs' individual performance relative to individual performance goals, and with respect to the named executive officers other than Mr. Kohrs, considered Mr. Kohrs' recommendations, which were based on his consideration of the named executive officers' individual performance relative to individual performance goals, and qualitatively determined that Ms. Diersen achieved 95%, and that Messrs. Kohrs, Joiner, Epinette and Klemz achieved 88%, 85%, 85%, and 95% of their respective individual performance goals and approved payouts at these percentages for the portion of the named executive officers' bonuses tied to individual performance goals. As a result of his termination of employment, Mr. Doty was not eligible to receive an annual incentive bonus based on 2010 performance.

For 2010, the payout percentages attributable to corporate performance represented 80% and individual performance represented 20% of the named executive officers' overall annual bonus, which resulted in payouts at approximately the following aggregate percentages:
 (i) Mr. Kohrs 80.55%, (ii) Ms. Diersen 81.96%, (iii) Mr. Joiner 79.96%, (iv) Mr. Epinett 79.96%, and (v) Mr. Klemz, 81.96%. Actual 2010 bonus amounts are set forth below in the Summary Compensation Table and were paid in February 2011.

Table of Contents**French Incentive Compensation Scheme**

In addition to participating in our annual bonus program, Mr. Epinette participates in an incentive compensation scheme on the same basis as other employees of our French operating subsidiary. This incentive compensation scheme enables our French operating subsidiary to provide its employees with a form of compensation that is efficient with respect to income tax and mandated social contributions in France, insofar as the payments made under the incentive compensation scheme, which receives preferential tax treatment, are exempted from social security contributions. Pursuant to the incentive compensation scheme, employees may receive an annual incentive payment equal to a specified percentage of base salary, up to certain statutory limits. In 2010, employees were eligible to receive up to 16% of base salary, up to a statutory limit of \$22,984. For 2010, annual incentive payments were dependent on the achievement of performance goals relating to revenue, Modified EBITDA, revenue over net value of implants and instruments and on-time delivery to market of certain new products. The following table sets forth the 2010 financial performance metrics for the incentive compensation scheme and the range of possible payouts for Mr. Epinette based on the performance achieved. If performance achieved falls between the threshold and target/maximum levels, actual payout percentages are determined on a sliding scale basis, with payouts starting at 0.25% of base salary for minimum performance achievement and capped at 4% of base salary for target/maximum achievement. The actual payout percentages and Mr. Epinette's actual 2010 incentive payment amount, which will be paid by July 2011, are not currently calculable, but are expected to be determined by the board during the third quarter of 2011.

Modified metrics(2)	Weight (% of payment tied to performance of this metric)	Performance targets(1)		Payout	
		Threshold	Target/max.(3)	Threshold (% of base salary)	Target/max. (% of base salary)
Modified Revenue	25%	\$203.2 million	\$239.0 million	0.25%	4%
Modified EBITDA(4)	25%	\$16.7 million	\$19.7 million	0.25%	4%
Modified Revenue/(Net Value of Implants and Instruments)(5)	25%	.91	1.97	0.25%	4%
On-time Delivery to Market of New Products(6)	25%	n/a	n/a	0.25%	4%

- (1) The performance targets were established based on an assumed foreign currency exchange rate of 1.45 U.S. dollars for 1 Euro, which represented an anticipated average rate of foreign exchange for 2010 and which was the rate of foreign exchange used by the Company for 2010 budgeting purposes.
- (2) The board of directors has historically determined incentive payment amounts after reviewing our unaudited financial statements for the applicable fiscal year, which are adjusted for changes to the foreign exchange rates and which are subject to discretionary adjustment by our board for items that are unusual and not reflective of normal operations. It is anticipated that the metrics used for determining the 2010 incentive payment amounts will be subject to foreign exchange adjustments and discretionary board adjustments and will differ from the figures reported in our 2010 audited financial statements.
- (3) Under the French incentive compensation scheme, the maximum possible payout is 16% of base salary, up to a statutory limit of \$22,984, which is based on 100% achievement of target levels. Therefore, target and maximum performance and payout amounts are the same for the purposes of the French incentive compensation scheme.
- (4) "Modified EBITDA" means our earnings before interest, taxes, depreciation and amortization, subject to adjustment as described in footnote(2).

Table of Contents

- (5) "Modified Revenue/(Net Value of Implants and Instruments)" means revenue, divided by the net value of our inventory of raw materials, semi-finished products, and finished goods inventory in warehouses and with customers, plus the net value of implants and instruments, subject to adjustment as described in footnote(2).
- (6) "On-Time Delivery to Market of New Products" means the timely release of certain new, strategic products by specific dates. The target/maximum payout amount with respect to this metric assumes the timely release of all new products scheduled to be delivered for a given year, whereas the threshold payout amount is determined by dividing 4% (the target/maximum payout for this metric) by the number of new products scheduled to be delivered for a given year.

Long-Term Equity Compensation

Stock Option Plan

We have historically maintained a stock option plan, in an effort to align the equity ownership of our employees with the long-term interests of our shareholders, under which, our named executive officers and other employees have been eligible to receive option grants. We believe that options effectively incentivize our employees to maximize Company performance, as the value of awards is directly tied to an appreciation in the value of our shares, and provide an effective retention mechanism as a result of the applicable vesting mechanics of the options. As of February 2, 2011, we will not make further grants under our stock option plan, and equity-based awards will instead be granted under our new stock incentive plan, as described below.

In 2010, each of our named executive officers (other than Mr. Doty) received a grant of options. The number of options granted to each named executive officer (other than Mr. Klemz and Ms. Diersen) was determined by our board of directors, based upon recommendations from Mr. Carney and, other than with respect to his grants, the Chief Executive Officer, based on each executive's position, role and responsibilities, and individual and overall Company performance as determined by the board of directors. In determining the actual number of options awarded to Mr. Kohrs during 2010, the board of directors considered our past grant practices and targeted an ownership rate appropriate for Mr. Kohrs' current equity held and the relative percentage of total equity that his current equity holdings and proposed option grant would represent, and determined that an award to Mr. Kohrs of 83,333 options was consistent with our overall compensation objectives. Those objectives include providing a substantial portion of named executive officer compensation in the form of equity-based compensation and aligning our named executive officers' interests with those of our shareholders. Historically (and in 2010) the board of directors has determined the actual number of options awarded to our named executive officers during a given fiscal year by assessing targeted long-term ownership levels and the relative percentage of total equity outstanding that each option grant represents. Consistent with past practices, Mr. Klemz was granted 83,333 options in 2010, and Ms. Diersen, 150,000 options, in connection with the commencement of their employment. The board of directors and our Chief Executive Officer determined the number of options awarded to Mr. Klemz and Ms. Diersen based upon their respective roles and responsibilities and based on a desire to align their interests with those of our shareholders at the outset of their employment by providing them with a grant of long-term equity-based compensation. As new hires, Mr. Klemz and Ms. Diersen received option grants that were larger than the grants made to our other named executive officers in 2010, which is consistent with our historical practice of providing new hires with larger grants than the annual grants provided to our other named executive officers, in order to provide such individuals with a stake in our future which corresponds to the stake of each of our shareholders at the outset of their employment. Our stock option plan provides that, except as may otherwise be determined by the board of directors, options vest over a four-year period, with 25% vesting on the first anniversary of the applicable vesting commencement date and the remaining 75% vesting on a pro-rata basis on each quarterly anniversary of the applicable vesting commencement date over the three-year period thereafter. Option holders will

Table of Contents

forfeit their outstanding options to the extent they, as determined by our board of directors, engage in competitive activities (as defined in the stock option plan) during the course of their employment or during the six-month period following their termination. Additionally, on February 2, 2011, the stock option plan was amended to provide that in the event a change in control occurs, unless otherwise provided by our compensation committee, any outstanding awards, whether vested or unvested, will be accelerated as of the consummation of the change in control. We believe that granting options subject to the vesting schedule described above provides us with an effective mechanism to incentivize and to retain our named executive officers and to align their interest with the long-term interests of our shareholders.

For more information on the stock option plan, see the discussion below under "Narrative Disclosure to Summary Compensation Table and Grant of Plan-Based Awards Table Stock Option Plan."

Stock Incentive Plan

At our general meeting of shareholders on August 26, 2010, our shareholders approved a new stock incentive plan that will afford more flexibility to our compensation committee in 2011 by allowing grants of a wide variety of equity awards to our employees, including our named executive officers, directors, and consultants, including incentive and non-qualified options, stock appreciation rights, stock grants, stock unit grants, cash-based awards, and other stock based awards. The stock incentive plan is designed to assist us in attracting and retaining our employees, directors, and consultants, to provide an additional incentive to such individuals to work to increase the value of our ordinary shares, and to provide such individuals with a stake in our future which corresponds to the stake of each of our shareholders.

As of February 2, 2011, we ceased making grants under our stock option plan. The stock incentive plan reserves for issuance a number of ordinary shares equal to the sum of (i) the number of ordinary shares available for grant under the stock option plan as of February 2, 2011 (not including issued or outstanding shares granted pursuant to options under the stock option plan as of such date) and (ii) the number of ordinary shares forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination following February 2, 2011 of an option outstanding as of February 2, 2011 under the stock option plan. As of February 2, 2011, 1,199,296 ordinary shares remained available for grant under the stock option plan, and there were 3,747,888 shares covering outstanding awards as of such date. For purposes of determining the remaining ordinary shares available for grant under the stock incentive plan, to the extent that an award expires or is cancelled, forfeited, settled in cash, or otherwise terminated without a delivery to the participant of the full number of ordinary shares to which the award related, the undelivered ordinary shares will again be available for grant. Similarly, ordinary shares withheld or surrendered in payment of an exercise price or taxes relating to an award under the stock incentive plan shall be deemed to constitute shares not delivered to the participant and shall be deemed to again be available for awards under the stock incentive plan. The total number of ordinary shares available for issuance under the stock incentive plan will be subject to adjustment in the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin off) or any other similar change in our corporate structure or ordinary shares.

The stock incentive plan provides for the grant of both incentive stock options, within the meaning of Section 422(b) of the Internal Revenue Code of 1986, as amended, and non-qualified stock options. The stock incentive plan also permits the grant of ordinary shares subject to vesting restrictions, stock unit grants, which represent the right to receive cash based on the value of ordinary shares in the future, stock appreciation rights grants, which are rights to receive an amount equal to the value in cash or in ordinary shares of the appreciation in the ordinary shares over a specified period, and grants

Table of Contents

of other awards that may be denominated in, payable in, valued in whole or in part by reference to or otherwise based on or related to our ordinary shares.

In the event of a change in control (as defined in the stock incentive plan), unless otherwise provided by the compensation committee, any outstanding awards, whether vested or unvested, will be accelerated as of the consummation of the change in control. Alternatively, the compensation committee may determine that outstanding awards will be cancelled as of the consummation of the change in control and that holders of cancelled awards will receive a payment in respect of such cancellation based on the amount of per-share consideration being paid in connection with the change in control less, in the case of options and other awards subject to exercise, the applicable exercise price.

Our board of directors has the ability to amend the stock incentive plan or any awards granted thereunder at any time, provided that no amendment will be made that impairs the rights of the holder of any award. Our board of directors may also suspend or terminate the stock incentive plan at any time, and, unless sooner terminated, the stock incentive plan shall terminate on the day before the tenth (10th) anniversary of the date the stock incentive plan was adopted by our shareholders.

Employee Stock Purchase Plan

At our general meeting of shareholders on October 28, 2010, our shareholders approved a new employee stock purchase plan that will provide our employees, including our named executive officers, and employees of certain designated subsidiaries with an opportunity to purchase our ordinary shares at a discount on a tax-qualified basis through payroll deductions in 2011. The employee stock purchase plan has been designed to qualify as an "employee stock purchase plan" under Section 423 of the U.S. Internal Revenue Code.

A total of 333,333 ordinary shares have been reserved for issuance under the employee stock purchase plan, subject to adjustment in the event of certain changes in our corporate structure or ordinary shares. The employee stock purchase plan provides for consecutive offering periods, during which participating employees may elect to have between 1% and 10% of their compensation withheld and applied to the purchase of ordinary shares at the end of the period. Unless otherwise determined by our compensation committee before an offering period, the purchase price will be 85% of the fair market value of the ordinary shares at the end of the offering period.

The stock purchase plan is administered by our compensation committee. Our board of directors has the ability to suspend, terminate, or amend the employee stock purchase plan at any time, although the board of directors generally may not amend the employee stock purchase plan in such a way that would adversely affect the rights of any participating employee without that employee's consent or shareholder approval. Unless sooner terminated, the employee stock purchase plan will terminate on the day before the tenth (10th) anniversary of the date the employee stock purchase plan is approved by the board.

Retirement Benefits

In 2010, each of our named executive officers had the opportunity to participate in retirement plans maintained by our operating subsidiaries, including our U.S. operating subsidiary's 401(k) plan and, with respect to Mr. Epinette, our French operating subsidiary's government-mandated pension plan and a government-mandated pension plan for managerial staff, or the *Retraite Complémentaire*, on the same basis as our other employees. We believe that these plans provide an enhanced opportunity for our named executive officers to plan for and meet their retirement savings needs. Mr. Epinette also participated in our French operating subsidiary's defined contribution pension plan for key employees, or the *Retraite Supplémentaire* on the same basis as other key employees. In 2010, pursuant to the *Retraite Supplémentaire*, our French operating subsidiary made contributions equal to approximately 6.5% of Mr. Epinette's base salary on Mr. Epinette's behalf. The *Retraite*

Table of Contents

Supplémentaire is intended to supplement the state pension plans mandated by French labor laws and to provide participants with a form of compensation that is efficient with respect to income tax and mandated social contributions.

Perquisites and Other Benefits

In 2010, our named executive officers were eligible to receive the same benefits, including life and health benefits, that were available to all employees. We also provided certain additional perquisites to our named executive officers, on a case-by-case basis, including relocation and automobile allowances. We paid for Ms. Diersen's moving and temporary housing expenses associated with her relocation upon joining the Company, which we believed were a necessary inducement for her to join the Company. We also provide Mr. Epinette with an automobile allowance on the same basis as other key employees of our French operating subsidiary pursuant to a Company policy, which we believe is necessary in light of the competitive market for talent in our industry.

Employment/Severance, Non-Competition and Non-Solicitation Agreements

Each of our named executive officers is entitled to receive severance benefits upon certain qualifying terminations of employment, pursuant to the provision of such executive's employment agreement. Additionally, pursuant to their agreements, each of our named executive officers is entitled to receive certain enhanced severance benefits upon certain qualifying terminations of employment occurring within twelve months of a Change in Control (as such term is defined in the employment agreements). These severance arrangements were initially offered to induce the named executive officers to accept or continue employment with the Company and are primarily intended to retain our named executives, provide consideration to an executive for certain restrictive covenants that apply following a termination of employment and to provide continuity of management in connection with a threatened or actual Change in Control transaction. Additionally, we entered into the employment agreements because they provide us valuable protection by subjecting the named executive officers to restrictive covenants that prohibit the disclosure of confidential information during and following their employment and limit their ability to engage in competition with us or otherwise interfere with our business relationships following their termination of employment. For more information on our employment agreements and severance arrangements with our named executive officers, see the discussions below under "Narrative Disclosure to Summary Compensation Table and Grant of Plan-Based Awards Table Employment Agreements" and "Potential Payments Upon a Termination or Change in Control."

In connection with his termination of employment, which became effective on February 19, 2010, Mr. Doty and our U.S. operating subsidiary entered into a separation agreement pursuant to which, in exchange for his execution of a general release, Mr. Doty became entitled to the severance payments and benefits described below under "Narrative Disclosure to Summary Compensation Table and Grant of Plan-Based Awards Table Separation Agreement with Michael Doty."

Compensation Risk Management

Risk Management

Our board of directors has reviewed our overall compensation policies and practices to determine whether those policies and practices are reasonably likely to have a material adverse effect on us and

Table of Contents

has concluded that they are not reasonably likely to have a material adverse effect on us based on the following analysis:

Base Compensation

Base compensation is a fixed portion of overall compensation that is set based on factors such as the scope of an employee's responsibilities and market practices, and which provides income regardless of our short-term performance. Our board of directors does not believe that base compensation creates an incentive for our employees to take undue risks.

Bonus Programs

Bonuses are intended to compensate our employees for achieving corporate performance goals and individual performance goals. We maintain several incentive compensation programs, including our annual bonus program and an incentive compensation scheme for the benefit of employees of our French operating subsidiary, which is maintained in accordance with French labor laws. Our bonus programs are designed to focus employees on achieving annual goals that are important to our success. The fact that bonuses are awarded based on the achievement of corporate performance goals may encourage some risk-taking behavior, but this risk is mitigated by the fact that awards are based on the achievement of a balanced mix of several broad-based criteria. Additionally, in the case of our annual bonus program, a portion of the annual bonus is awarded based on the achievement of qualitative individual performance goals, and in the case of our French incentive compensation scheme, payments are limited by local law and generally do not represent a significant portion of our employees' total compensation. For these reasons, our board of directors believes that our bonus programs appropriately balance risk and reward, and do not encourage employees to take unnecessary or excessive risks which could have a material adverse effect on us.

Long-Term Equity Compensation

We award certain employees equity compensation in the form of options in an effort to align the equity ownership of employees with the long-term interests of our shareholders. Our board of directors believes that long-term equity compensation discourages our employees from engaging in unnecessary or excessive risk taking, because the ultimate value of the equity awards, which are subject to four-year vesting schedules, is determined based on the long-term appreciation in value of our shares.

Retirement, Health, and Other Welfare Benefits

Our employees are eligible to participate in retirement plans maintained by us and by our operating subsidiaries abroad. Our board of directors does not believe that such programs encourage our employees to take unnecessary or excessive risks which could have a material adverse effect on us, because they represent a small portion of overall compensation, are unrelated to our short-term performance, and are generally limited by local laws. Our board of directors does not believe that the health and welfare benefits we provide to our employees create an incentive for our employees to take undue risks, because the value of these benefits is unrelated to our short-term performance.

Severance Benefits

Our executive officers and our employees are eligible to receive severance payments and benefits upon certain terminations of employment pursuant to their employment agreements, our severance policy, or severance policies maintained by our operating subsidiaries abroad in accordance with local laws, which payments and benefits are limited by the terms of such applicable agreements, policies, and laws. Our board of directors does not believe that our severance policies and practices create an incentive for our employees to take undue risks.

Table of Contents**Perquisites**

We provide our executive officers and certain other employees with perquisites, including, in the case of Mr. Epinette, an automobile allowance. Our board of directors does not believe that the perquisites we provide are excessive, or that they encourage employees to take unnecessary or excessive risks.

After considering the risk implications of each element of our overall compensation program, our board of directors determined that the only components of employee compensation that could pose risks are the annual bonus program and the incentive programs. These programs encourage some level of risk taking by our employees; however, we believe that the risk is well managed and the level of risk acceptable, particularly in light of the balanced mix of fixed and variable elements, and of short- and long-term elements, in our overall compensation program. For these reasons, our board of directors concluded that our overall compensation policies and practices are not likely to have a material adverse effect on us.

Executive Compensation**Summary Compensation Table**

The following table shows compensation of our principal executive officer, our principal financial officers and other named executive officers for the fiscal years ending December 27, 2009 and January 2, 2011.

Name and principal position	Year	Salary (\$)	Option awards(2)(\$)	Non-equity incentive plan compensation (\$)	All other compensation (\$)	Total (\$)
Douglas W. Kohrs	2010	490,333(1)	913,625	236,994(3)	0	1,640,952
President, Chief Executive Officer and Director(4)	2009	477,210	478,661	289,189	0	1,245,060
Michael J. Doty(4)	2010	44,315	191,960(6)	0(3)	283,795(5)	520,070
Former Global Chief Financial Officer	2009	315,667	119,665	131,317	0	566,649
Carmen L. Diersen(4)	2010	172,500	1,711,935	70,691(3)	184,866(9)	2,139,992
Global Chief Financial Officer						
Andrew E. Joiner	2010	327,417	456,825	130,901(3)	6,701	921,844
Vice President and General Manager, U.S. Commercial Operations	2009	304,500	239,330	156,818	0	700,648
Stéphan Epinette(7)	2010	278,171	365,450	67,974(3)	95,847(8)	807,442
Vice President, International Commercial Operations	2009	278,866	478,661	109,667	78,418	945,612
Kevin M. Klemz(4)	2010	81,865	899,925	26,839(3)	0	1,008,629
Vice President, Chief Legal Officer and Secretary						

(1) Effective as of August 26, 2010, five percent of Mr. Kohrs's annual base salary was allocated to his service as a member of our board of directors.

(2) The amounts shown in the "Option Awards" column represent the aggregate grant date fair value of equity awards granted in 2009 and 2010, respectively, computed in accordance with FASB ASC Topic 718. The fair value of each option grant is estimated on the date of grant using the

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Black-Scholes option pricing model using the following weighted-average assumptions for options granted to all employees:

	2009	2010
Risk-free interest rate	1.8%	2.26%
Expected life in years	6.0	5.8
Expected volatility	41.8%	49.8%
Expected dividend yield	0.0%	0.0%

- (3) Reflects the amount of annual incentive bonuses paid to our named executive officers in respect of 2010 performance, but paid in February 2011. Mr. Epinette's annual incentive bonus was calculated using a base salary of \$275,303, instead of the \$278,171 reported in the Summary Compensation Table, as the amount of base salary reported in the Summary Compensation Table includes approximately \$2,868 relating to Mr. Epinette's company car and vacation allowances that are otherwise includible in Mr. Epinette's gross taxable income pursuant to French tax law. For Mr. Epinette, the bonus payable pursuant to the French incentive compensation scheme based on 2010 performance is not currently calculable, but is expected to be determined during the third quarter of 2011, at which time such amounts will be disclosed under Item 5.02(f) on Form 8-K. As a result of his termination of employment, Mr. Doty was not eligible to receive an annual incentive bonus based on 2010 performance.
- (4) Mr. Doty's tenure as Chief Financial Officer of Tornier, Inc. terminated as of February 19, 2010. Ms. Diersen joined the Company on June 21, 2010. Mr. Kohrs served as the Company's principal financial officer during the period between Mr. Doty's departure and Ms. Diersen joining the Company. Mr. Klemz joined the Company on September 13, 2010.
- (5) Reflects severance payments of \$271,352, which represents the cost of base salary continuation through January 2, 2011, and benefits of \$12,443, which represents the cost of continued coverage on our health plans through January 2, 2011, payable to Mr. Doty in connection with his termination of employment.
- (6) Reflects the incremental fair value, computed as of February 19, 2010, in accordance with FASB ASC Topic 718, with respect to the extension of the exercise period applicable to Mr. Doty's vested, unexercised equity awards. The incremental fair value with respect to the modified options was estimated on the modification date using the Black-Scholes option pricing model using the following weighted-average assumptions:
- | | |
|-------------------------|------|
| Risk-free interest rate | 0.4% |
| Expected life in years | 1.5 |
| Expected volatility | 55% |
| Expected dividend yield | 0.0% |
- (7) Mr. Epinette's cash compensation was paid in Euro. The foreign currency exchange rate of 1.3278 U.S. dollars for 1 Euro, which reflects an average conversion rate for 2010, was used to calculate Mr. Epinette's base salary and all other compensation amounts for 2010. The foreign currency exchange rate of 1.3667 U.S. dollars for 1 Euro, the spot conversion rate on February 22, 2011, was used to calculate his annual incentive bonus, which was paid in February 2010.
- (8) Consists of \$4,732 in contributions to the French government-mandated pension plan, \$44,920 in contributions to our French operating subsidiary's Retraite Complémentaire on Mr. Epinette's behalf, \$18,031 in contributions to our French operating subsidiary's Retraite Supplémentaire on Mr. Epinette's behalf and \$28,164 related to automobile expenses. The foreign currency exchange rate of 1.3278 U.S. dollars for 1 Euro, which reflects an average conversion rate for 2010, was used to calculate Mr. Epinette's all other compensation amounts for 2010.

Table of Contents

(9)

Consists of relocation perquisites including moving costs of \$29,253, payment of real estate taxes associated with the sale of Ms. Diersen's prior residence of \$14,313, payment of legal fees associated with the sale of Ms. Diersen's prior residence of \$2,475, payment of real estate fees associated with the sale of Ms. Diersen's prior residence of \$66,075, payment of closing costs associated with the sale of Ms. Diersen's prior residence of \$4,699, family travel costs of \$4,245, temporary housing costs of \$17,250, gross-up of compensation for taxes payable on the above items of \$44,118, and \$2,438 in contributions to our U.S. operating subsidiary's 401(k) Plan on Ms. Diersen's behalf.

Grant of Plan-Based Awards

The following table sets forth summary information regarding all grants of plan-based awards made to our named executive officers for the year ended January 2, 2011.

Name(1)	Grant date	Estimated future payouts under non-equity incentive plan awards (\$)			All other option awards: number of securities underlying options (#)	Exercise or base price of option awards (\$/share)(4)	Grant date fair value of option awards(5)
		Threshold(2)	Target	Maximum(3)			
Douglas W. Kohrs	3/3/2010	5,884	294,200	411,880			
	6/3/2010				83,333	22.50	913,625
Michael J. Doty	2/19/2010						191,960(6)
Carmen L. Diersen	6/21/2010	1,725	86,250	120,750			
	6/21/2010				150,000	22.50	1,711,935
Andrew E. Joiner	3/3/2010	3,274	163,708	229,192			
	6/3/2010				41,666	22.50	456,825
Stéphan Epinette(7)	3/3/2010	1,669(9)	83,451	116,832			
	6/25/2010(8)	695	22,984	22,984			
	6/3/2010				33,333	22.50	365,450
Kevin M. Klemz	9/13/2010	655	32,746	45,844			
	10/28/2010				83,333	22.50	899,925

(1)

All of our named executive officers (other than Mr. Doty) were granted non-equity incentive plan awards pursuant to our 2010 annual bonus scheme, and were granted stock options pursuant to our stock option plan. Mr. Epinette was also granted a non-equity incentive plan award pursuant to our French operating subsidiary's incentive compensation scheme.

(2)

The threshold amount for awards payable under our annual bonus program and our French operating subsidiary's incentive compensation scheme assumes that the threshold level of the lowest weighted financial performance objective has been satisfied.

(3)

Maximum amounts reflect payout of the portion of annual bonus tied to corporate financial performance objectives at a rate of 150% of target and the portion of the annual bonus tied to individual performance objectives at a rate of 100% of target under our annual bonus program. Target and maximum payout amounts are the same for the purposes of the French incentive compensation scheme.

(4)

The exercise price of the options was set at the fair market value of one share of our ordinary shares at the time of the grant, with fair market value being determined by our board of directors in good faith.

(5)

Edgar Filing: Tornier N.V. - Form 10-K

The amounts shown in the "Option Awards" column represent the aggregate grant date fair value of equity awards granted in 2010, computed in accordance with FASB ASC Topic 718. See

Table of Contents

footnote(2) to the Summary Compensation Table for a discussion of valuation assumptions for the aggregate grant date fair values.

- (6) Reflects the incremental fair value, computed as of February 19, 2010, in accordance with FASB ASC Topic 718, with respect to the extension of the exercise period applicable to Mr. Doty's vested, unexercised equity awards. See footnote (6) to the Summary Compensation Table for a discussion of valuation assumptions for the incremental modification date fair value.
- (7) The foreign currency exchange rate of 1.3278 U.S. dollars for 1 Euro, which reflects an average conversion rate for 2010, was used to calculate Mr. Epinette's target and maximum awards in respect of annual bonus and payments under the French incentive compensation scheme.
- (8) The terms of the 2010 French incentive compensation scheme were governed by an agreement entered into by our French operating subsidiary on June 25, 2010. Awards set forth on this line represent awards granted to Mr. Epinette pursuant to our French operating subsidiary's incentive compensation scheme.
- (9) Awards set forth on this line represent awards granted to Mr. Epinette pursuant to our annual bonus program.

Narrative Disclosure Relating to Summary Compensation Table and Grants of Plan-Based Awards Table

Employment Agreements

Tornier, Inc., our U.S. operating subsidiary, is a party to employment agreements with Messrs. Kohrs, Joiner, and Klemz, and Ms. Diersen, which agreements are substantially the same other than differences in base salary, target annual bonus percentages and severance. The agreements have specified terms of three years, subject to automatic renewal for one-year terms unless either party provides 60 days' advance notice of their desire not to renew. Under the agreements, each executive is entitled to an enumerated base salary, subject to increase but not decrease, is eligible to receive an annual bonus with a target bonus equal to an enumerated percentage of base salary (60% for Mr. Kohrs, 50% for Mr. Joiner, 50% for Ms. Diersen, and 40% for Mr. Klemz), and is entitled to participate in the employee benefit plans and arrangements that we generally maintain for our senior executives. If an executive's employment is terminated by Tornier, Inc. without "cause" (as such term is defined in the employment agreements), in addition to any accrued but unpaid salary and benefits through the date of termination, the executive will be entitled to base salary and health and welfare benefit continuation for twelve months following termination, and, in the event their employment is terminated without cause due to non-renewal of their employment agreements by Tornier, Inc., the executives will also be entitled to a payment equal to their pro-rata annual bonus for the year of termination. In the event any of Messrs. Kohrs, Joiner, Klemz's, or Ms. Diersen's, employment is terminated without cause or by the executive for "good reason" (as such term is defined in the employment agreements) within twelve months following a change in control, the executives will be entitled to receive accrued but unpaid salary and benefits through the date of termination, a lump-sum payment equal to their base salary plus target bonus for the year of termination, health and welfare benefit continuation for twelve months following termination and accelerated vesting of all unvested options. In addition, Mr. Kohrs' agreement provides that in the event the payments and benefits to which he is entitled pursuant to the agreement become subject to the excise tax under Section 4999 of the Internal Revenue Code of 1986, as amended, he will be entitled to a "gross-up" payment in order to cover such tax liability. The agreements also contain covenants intended to protect against the disclosure of confidential information during and following an executive's employment, as well as restrictions on engaging in competition with Tornier, Inc. or otherwise interfering with our business relationships, which extend through the first anniversary of an executive's termination of employment for any reason.

Table of Contents

Tornier SAS, our French operating subsidiary, is also a party to an employment agreement with Mr. Epinette, which does not have a specified term, but which may be terminated by either party in accordance with local law, and which is substantially similar to the employment agreements described above with respect to base salary, annual target bonus (30% of base salary), benefit participation and non-compete obligations. Pursuant to the agreement and French labor laws, Mr. Epinette is entitled to receive certain payments and benefits following a voluntary or involuntary termination of employment, including an amount equal to twelve months' gross monthly salary, which is payable as consideration for the restrictive covenants contained in the agreement, a payment equal to Mr. Epinette's French incentive compensation scheme payment for the year of his termination and, in the case of an involuntary termination of employment, a severance payment payable pursuant to French law, the amount of which is determined based on Mr. Epinette's gross monthly salary and years of service with Tornier SAS. If Mr. Epinette is terminated for reasons other than negligence or serious misconduct following a change in control (as such term is defined in the employment agreement), he is entitled to gross monthly salary continuation and health and welfare benefit continuation for twelve months following termination of employment, accelerated vesting of all unvested options, as well as a payment equal to Mr. Epinette's annual target bonus and French incentive compensation scheme payment for the year of his termination. Pursuant to French law, gross monthly salary represents the average salary Mr. Epinette received during the twelve-month period preceding his termination and includes the amount of any annual incentive bonus payable to Mr. Epinette during such period pursuant to our annual bonus program.

Separation Agreement with Michael Doty

Our U.S. operating subsidiary entered into a separation agreement with Mr. Doty in connection with his termination of employment, which became effective on February 19, 2010, pursuant to which, in exchange for his execution of a general release, Mr. Doty became entitled to the severance payments and benefits payable to him in the event of an involuntary termination of employment without cause pursuant to the employment agreement to which he was a party with the Company prior to his termination of employment, which was substantially the same as the agreements with Messrs. Joiner and Klemz, and Ms. Diersen, other than differences in base salary, target annual bonus percentages and severance. The cost of the separation agreement includes \$315,667 of base salary and continued coverage on our health plans through February 19, 2011, with the full cost of such coverage, \$13,575, being borne by the Company. The exercise period applicable to Mr. Doty's vested, unexercised options was extended to August 19, 2011 pursuant to the agreement. Mr. Doty's severance payments totaling \$315,667, less applicable withholding and related taxes, will be made semi-monthly over a period of one year from the date of termination. Mr. Doty is restricted from engaging in competition with us or otherwise interfering with our business until the first anniversary of his termination.

Stock Option Plan

Effective as of July 18, 2006, we adopted the stock option plan, which is designed to assist in attracting, retaining, motivating and rewarding eligible employees, directors and consultants, and promoting the creation of long-term value for our stockholders by closely aligning the interests of participants with those of such stockholders, by allowing grants of options to purchase shares of our common stock to such participants. Effective as of February 2, 2011, equity awards will be granted under our new stock incentive plan, which is discussed above under "Components of Compensation for 2010 Long-Term Equity Compensation Stock Incentive Plan," and no further grants will be made under the stock option plan.

Table of Contents

Our board of directors administers the stock option plan and is authorized to, among other things, designate participants, grant options, determine the terms and conditions relating to options, including vesting, prescribe option agreements, interpret the stock option plan, establish, amend and rescind any rules and regulations relating to the stock option plan, and to make any other determinations that it deems necessary or advisable for the administration of the stock option plan. Our board of directors may also delegate to our officers or employees, or other committees, subject to applicable law, the authority, subject to such terms as our board of directors determines appropriate, to perform such functions, including but not limited to administrative functions, including the appointment of agents to assist in the administration of the stock option plan. Any action of our board of directors (or its authorized delegates) will be final, conclusive and binding on all persons, including participants and their beneficiaries.

Our stock option plan reserves 5,000,000 shares of our ordinary shares for issuance, subject to adjustment in the event of any stock dividend or split, reorganization, recapitalization, merger, share exchange or any other similar corporate transaction or event. For purposes of determining the remaining ordinary shares available for grant under the stock option plan, to the extent that an option expires or is canceled, forfeited, settled in cash or otherwise terminated without a delivery to the participant of the full number of ordinary shares to which the option related, the undelivered ordinary shares will again be available for grant. Similarly, ordinary shares withheld in payment of the exercise price or taxes relating to an option and shares equal to the number surrendered in payment of any exercise price or taxes relating to an option shall be deemed to constitute shares not delivered to the participant and shall be deemed to again be available for options under the stock option plan.

The board of directors may, in the event of a Corporate Event (as defined in the stock option plan and which, for example includes a change in control or a reorganization of the Company), in its sole discretion, provide for adjustments or substitutions as to the number, price or kind of shares or other consideration subject to outstanding options, or provide for the termination of an option and the payment of a cash amount in exchange for the cancellation of an option. Additionally, our stock option plan was amended as of February 2, 2011, to provide that in the event a Change in Control (as defined in the stock option plan) occurs, unless otherwise provided by our compensation committee, any outstanding options, whether vested or unvested, will be accelerated as of the consummation of such Change in Control. The board of directors has the ability to amend or terminate the stock option plan at any time, provided that no amendment or termination will be made (i) that impairs the rights of the holder of any option outstanding on the date of such amendment or termination or (ii) without satisfying any applicable shareholder approval requirements. The board of directors may also suspend or terminate the stock option plan at any time, and, unless sooner terminated, the stock option plan will terminate on July 18, 2016.

The terms of the stock option plan restrict a participant's ability to transfer shares acquired pursuant to the exercise of options granted thereunder until the expiration of the 180-day period following the occurrence of an initial public offering of our ordinary shares. The stock option plan contains provisions which provide our institutional investors with drag along rights and us with repurchase rights, which rights will terminate upon the occurrence of an initial public offering of our ordinary shares.

Table of Contents**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth summary information regarding the outstanding equity awards held by our named executive officers at January 2, 2011.

Name	Number of securities underlying unexercised options(1) (#) exercisable	Number of securities underlying unexercised options(1) (#) unexercisable	Option exercise price (\$)	Option expiration date
Douglas W. Kohrs	583,333		13.38	7/18/2016
	355,808	23,720	13.89	2/26/2017
	98,958	59,375	16.98	4/24/2018
	29,166	37,500	16.98	2/1/2019
		83,333	22.50	2/1/2020
Michael Doty(4)	87,500		13.89	8/19/2011
	21,875		16.98	8/19/2011
	4,166		16.98	8/19/2011
Carmen L. Diersen		150,000	22.50	6/21/2020
Andrew Joiner	52,083	31,250	16.98	4/25/2018
	14,583	18,750	16.98	2/1/2019
		41,666	22.50	2/1/2020
Stéphan Epinette	29,166	37,500	16.98	3/26/2019
		33,333	22.50	2/1/2020
Kevin M. Klemz		83,333	22.50	9/13/2020

(1) All options were granted under the stock option plan. Our named executive officers did not exercise any outstanding options during 2010.

(2) 25% of the options vest on the first anniversary of the applicable vesting commencement date, and the remaining 75% of the options vest on a pro-rata basis on each quarterly anniversary of the applicable vesting commencement date over the three-year period following the first anniversary of the vesting commencement date. The vesting commencement date for each option is generally the date which is ten years earlier than the option expiration date listed on the table. Our named executive officers' unvested options will become fully vested as follows: (i) **Mr. Kohrs** for options expiring on February 26, 2017, 23,720 options vest on February 26, 2011, for options expiring on April 24, 2018, 9,896 options vest on each April 25, July 23, October 23 and January 23 through April 24, 2012 (9,894 options will vest on April 24, 2012), for options expiring on February 1, 2019, 4,166.625 options vest on each May 1, August 1, November 1 and February 1 through February 1, 2013, and for options expiring on February 1, 2020, 20,833.25 options vest on February 1, 2011, and 5,208.3125 options vest on each May 1, August 1, November 1 and February 1 occurring thereafter through February 1, 2014; (ii) **Mr. Doty** all vesting with respect to Mr. Doty's unvested options ceased as of February 19, 2010, in connection with his separation; (iii) **Ms. Diersen** for options expiring on June 21, 2020, 37,500 options vest on June 21, 2011, and 9,375 options vest on each September 21, December 21, March 21 and June 21 occurring thereafter through June 21, 2014, (iv) **Mr. Joiner** for options expiring on April 25, 2018, 5,208.3125 options vest on each April 25, July 23, October 23 and January 23 through April 24, 2012, for options expiring on February 1, 2019, 2,083.3125 options vest on each May 1, August 1, November 1 and February 1 through February 1, 2013, and for options expiring on February 1, 2020, 10,416.5 options vest on February 1, 2011, and 2,604.125 options vest on each May 1, August 1, November 1 and February 1 occurring thereafter through February 1, 2014; (v) **Mr. Epinette** for options expiring on March 26, 2019, 4,166.625 options vest on each June 26, September 26, December 26 and March 26 through March 26, 2013, and for options expiring on February 1, 2020, 8,333.25 options vest on February 1, 2011, and 2,083.3125 options vest on each May 1, August 1, November 1 and

Table of Contents

February 1 occurring thereafter through February 1, 2014; and (vi) **Mr. Klemz** for options expiring on September 13, 2020, 20,833.25 options vest on September 13, 2011, and 5,208.3125 options vest on each December 13, March 13, June 13 and September 13 occurring thereafter through September 13, 2014.

(3)

The exercise price of the options were set at the fair market value of a share of our ordinary shares at the time of the grant, with fair market values being determined by our board of directors in good faith.

(4)

All unvested options held by Mr. Doty as of February 19, 2010 were forfeited in connection with the separation agreement.

Potential Payments Upon a Termination or Change in Control

Pursuant to the employment agreements with our named executive officers, upon certain terminations of employment, our named executive officers are entitled to payments of compensation and benefits as described above under "Narrative Disclosure to Summary Compensation Table and Grant of Plan-Based Awards Table Employment Agreements." The table below reflects the amount of compensation and benefits payable to each named executive officer in the event of (i) any termination (including for cause) or resignation, or a voluntary/for cause termination, (ii) an involuntary termination without cause, (iii) an involuntary termination without cause or a resignation for good reason within twelve months following a change in control, or a qualifying change in control termination, (iv) termination by reason of an executive's death and (v) termination by reason of an executive's disability. The amounts shown assume that the applicable triggering event occurred on January 2, 2011, and therefore are estimates of the amounts that would be paid to the named executive officers upon the occurrence of such triggering event. Mr. Doty is not included in the table below because he was not employed as of January 2, 2011. For more information regarding the amounts payable to Mr. Doty in connection with this termination, please refer to the discussion above under

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

"Narrative Disclosure to Summary Compensation Table and Grant of Plan-Based Awards Table Separation Agreement with Michael Doty."

Name	Type of payment	Triggering Events				
		Voluntary/ for cause termination (\$)	Involuntary termination without cause (\$)	Qualifying change in control termination (\$)	Death (\$)	Disability (\$)
Douglas W. Kohrs	Cash Severance(1)		490,333	490,333		
	Benefit					
	Continuation(2)		13,575	13,575		
	Target Bonus(3)			294,200		
	Equity					
	Acceleration(4)			738,984		
	Gross-Up			0		
	Total		503,908	1,537,092		
Carmen L. Diersen	Cash Severance(1)		325,000	325,000		
	Benefit					
	Continuation(2)		13,575	13,575		
	Target Bonus(3)			162,500		
	Equity					
	Acceleration(4)			0(5)		
	Total		338,575	501,075		
Andrew E. Joiner	Cash Severance(1)		327,417	327,417		
	Benefit					
	Continuation(2)		13,575	13,575		
	Target Bonus(3)			163,708		
	Equity					
	Acceleration(4)			276,000		
	Total		340,991	780,700		
Stéphan Epinette(6)	Cash Severance	360,628(8)	372,649(9)	721,256(10)		360,628(8)
	Benefit Continuation			6,975		
	Target Bonus(7)	22,984	22,984	105,840	22,984	22,984
	Equity					
	Acceleration(4)			207,000		
	Total	383,612	395,633	1,041,071	22,984	383,612
Kevin J. Klemz	Cash Severance(1)		270,000	270,000		
	Benefit					
	Continuation(2)		13,575	13,575		
	Target Bonus(3)			108,000		
	Equity					
	Acceleration(4)			0(5)		
	Total		283,575	391,575		

- (1) Includes the value of salary continuation for twelve months or payment of a lump sum equal to twelve months' salary following the executive's termination, as applicable.
- (2) Includes the value of medical, dental and vision benefit continuation for each executive and their family for twelve months following the executive's termination. With respect to a qualifying change in control termination, Tornier will bear the entire cost of coverage.
- (3)

Edgar Filing: Tornier N.V. - Form 10-K

Includes value of full target bonus for the year of the change in control.

(4)

Includes the value of acceleration of all unvested shares that are subject to options, based on a per share price of \$22.50, which is the value obtained in our most recent valuation.

(5)

The value of acceleration of all unvested shares that are subject to options held by Ms. Diersen and Mr. Klemz, all of which have an exercise price of \$22.50, is \$0, based on a per share price of \$22.50, which is the value obtained in our most recent valuation.

(6)

The foreign currency exchange rate of 1.3278 U.S. dollars for 1 Euro, which reflects an average conversion rate for 2010, was used to calculate Mr. Epinette's payments and benefits upon termination of employment.

Table of Contents

- (7) Includes amounts payable pursuant to the French incentive compensation scheme maintained by Tornier SAS assuming 100% achievement of applicable performance metrics. Pursuant to French law, participants receive their annual incentive payment for the year of their termination of employment for any reason. Upon a qualifying termination following a change in control, Mr. Epinette will also receive his full target annual bonus for the year of the change in control.
- (8) Reflects an amount equal to twelve months' gross monthly salary, which is payable as consideration for the restrictive covenants contained in Mr. Epinette's employment agreement (the "Restrictive Covenant Consideration"). Pursuant to French law, gross monthly salary represents the average salary Mr. Epinette received during the twelve-month period preceding his termination and includes the amount of annual incentive bonus payable to Mr. Epinette in 2010 in respect of 2009 performance pursuant to our annual bonus program.
- (9) Reflects, in addition to the Restrictive Covenant Consideration, an amount equal to one-fifth of Mr. Epinette's gross monthly salary, multiplied by his number of years of service with Tornier SAS, which is intended to reflect an amount payable pursuant to French law in the event of Mr. Epinette's involuntary termination of employment. Mr. Epinette will receive these benefits following any involuntary termination of employment, except for a termination involving serious or gross misconduct.
- (10) Reflects, in addition to the Restrictive Covenant Consideration, an amount equal to twelve months' gross monthly salary, which is intended to reflect an amount payable pursuant to Mr. Epinette's employment agreement in the event of an involuntary termination of employment within twelve months following a change in control.

Table of Contents**DIRECTOR COMPENSATION**

With the exception of Messrs. Tornier and O'Boyle, we did not pay our current directors any compensation for serving on our board of directors during 2010. While Mr. Kohrs did not receive additional compensation for his service as a director, a portion of his compensation was allocated to his service as a member of the board effective as of August 26, 2010. For more information regarding the allocation of Mr. Kohrs's compensation, please refer to footnote (1) to the Summary Compensation Table. The table below summarizes the compensation received by our non-employee directors for the year ended January 2, 2011.

Director Compensation Table

Name	Fees earned or paid in cash (\$)	Stock Awards (\$)(2)	Option Awards (\$)(4)	Total (\$)
Sean D. Carney				
Richard B. Emmitt				
Pascal E.R. Girin				
Kevin C. O'Boyle			565,935	565,935
Alain Tornier	19,917(1)	981,750(3)		1,001,667
Simon Turton				
Richard F. Wallman				
Elizabeth H. Weatherman				

- (1) The foreign currency exchange rate of 1.3278 U.S. dollars for 1 Euro, which reflects an average conversion rate for 2010, was used to calculate Mr. Tornier's cash compensation. The amount shown reflects meeting fees earned by Mr. Tornier in 2010, as described below.
- (2) The amount shown in the "Stock Awards" column represents the aggregate grant date fair value of stock awards granted in 2010, computed in accordance with FASB ASC Topic 718, which was estimated on the date of grant based on a per-share price of \$22.50 (which was equal to our estimate of the fair value of our ordinary shares at that time). As of January 2, 2011, our non-employee directors did not hold any shares of common stock subject to unvested stock awards.
- (3) The amount shown in the "Stock Awards" column for Mr. Tornier represents the aggregate grant date fair value of stock awards issued to Mr. Tornier on June 4, 2010, in respect of amounts owed to Mr. Tornier for past services performed under the terms of his consulting agreement. See footnote (2) above for a discussion of valuation assumptions for the aggregate grant date fair value.
- (4) The amount shown in the "Option Awards" column represents the aggregate grant date fair value of equity awards granted in 2010, computed in accordance with FASB ASC Topic 718. See footnote (2) to the Summary Compensation Table for a discussion of valuation assumptions for the aggregate grant date fair values. As of January 2, 2011, the aggregate number of shares of our common stock subject to outstanding options held by our non-employee directors was as follows: Mr. O'Boyle, 50,000 shares and Mr. Wallman, 34,375 shares.

Narrative Disclosure Relating to Director Compensation Table***Director Compensation***

With the exception of Messrs. Tornier and O'Boyle, we did not pay our current non-employee directors any compensation for serving on our board of directors during 2010. We did, however, reimburse all directors for expenses incurred in connection with their service on the board of directors,

Table of Contents

including reimbursement of expenses incurred in connection with attending board of directors' meetings. In 2010, in addition to receiving reimbursement for travel expenses, Mr. Tornier was eligible to receive meeting fees of €3,000 per meeting attended, and earned €15,000 in total meeting fees in 2010.

On July 31, 2006 we entered into a consulting agreement with Mr. Tornier, pursuant to which, in exchange for his services to us as a consultant, he was entitled to receive a consulting fee of €16,000 per month. Pursuant to the agreement, Mr. Tornier advised us and our executive officers with respect to investments, new opportunities for growth and general business matters. The agreement, which had a specified term of one year, was subject to automatic renewal for one-year terms unless either party provides three months' advance notice of their desire not to renew and contained covenants intended to protect against the disclosure of confidential information during and following the term of the agreement. On June 4, 2010, we issued 43,633 ordinary shares to KCH, a Swedish entity which is wholly owned by Mr. Tornier, having a value equal to €0.7 million (the total amount owed to Mr. Tornier for past services performed under the terms of the consulting agreement as of April 4, 2010), based on a per-share price of \$22.50 (which was equal to our estimate of the fair value of our ordinary shares at that time) and a foreign currency exchange rate of 1.3479 U.S. dollars for 1 Euro, the spot conversion rate on March 31, 2010. Mr. Tornier's consulting agreement was terminated effective as of March 31, 2010.

Option Grant

On June 3, 2010, our board of directors granted 50,000 stock options to Mr. O'Boyle pursuant to our stock option plan, with an exercise price of \$22.50 per share. The options are subject to the same vesting schedule as those granted to our named executive officers, that is, subject to continued service on the board of directors, 25% of the options vested on the first anniversary of the applicable vesting commencement date, and the remaining 75% of the options will vest on a pro-rata basis on each quarterly anniversary of the vesting commencement date over the three-year period following the first anniversary of the vesting commencement date.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information concerning the beneficial ownership of our ordinary shares as of March 7, 2011, by:

each of our directors, executive and other officers;

all of our directors, executive and other officers as a group; and

each person known by us to beneficially own more than 5% of our ordinary shares.

The calculations in the table below assume that there are 39,039,994 ordinary shares. Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. The shares that a shareholder has the right to acquire within 60 days, however, are not included in the computation of the percentage ownership of any other person.

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Unless otherwise indicated, the address for each listed shareholder is c/o Tornier N.V., Fred Roeskestraat 123, 1076 EE Amsterdam, the Netherlands.

	Ordinary shares beneficially owned	
	number	%
Directors, Executive and Other Officers:		
Douglas W. Kohrs(1)	1,877,866	4.7%
Carmen L. Diersen	17,500	*
Robert J. Ball(2)	146,874	*
Ralph E. Barisano, Jr.(3)	63,095	*
Stéphan Epinette(4)	45,278	*
Andrew E. Joiner(5)	94,270	*
Jamal D. Rushdy(6)	88,051	*
James C. Harber(7)	68,438	*
James E. Kwan(8)	125,590	*
Kevin M. Klemz		
Gregory Morrison		
Michael J. Doty(9)	123,571	*
Elizabeth H. Weatherman(10)	18,491,809	47.4%
Sean D. Carney(11)	18,799,507	48.2%
Pascal E.R. Girin		
Alain Tornier(12)	3,953,089	10.1%
Richard B. Emmitt(13)	3,383,101	8.7%
Kevin C. O'Boyle		
Richard F. Wallman(14)	54,708	*
All Directors, Executive and Other Officers as a Group	28,514,740	69.7%
Principal Shareholders:		
Warburg Pincus entities (TMG Holdings Coöperatief U.A.)(15)	18,491,809	47.4%
KCH Stockholm AB(16)	3,485,292	8.9%
Vertical Group, L.P.(17)	3,383,101	8.7%

*

Represents beneficial ownership of less than 1% of our stock.

- (1) Includes 425,015 ordinary shares, 307,698 ordinary shares held by STAK and options exercisable for 1,145,153 ordinary shares. Mr. Kohrs is a member of the board of directors of STAK, which board is authorized to act by the affirmative vote of two of its members. All shares indicated as owned by Mr. Kohrs that are held by STAK are included because of his affiliation with STAK. Mr. Kohrs disclaims all beneficial ownership in such shares.
- (2) Includes options exercisable for 146,874 ordinary shares.
- (3) Includes 3,720 ordinary shares and options exercisable for 59,375 ordinary shares.
- (4) Includes 1,528 ordinary shares and options exercisable for 43,750 ordinary shares.
- (5) Includes options exercisable for 94,270 ordinary shares.
- (6) Includes 2,427 ordinary shares and options exercisable for 85,624 ordinary shares.
- (7)

Edgar Filing: Tornier N.V. - Form 10-K

Includes 1,043 ordinary shares and options exercisable for 67,395 ordinary shares.

(8)

Includes 384 ordinary shares and options exercisable for 125,206 ordinary shares.

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

- (9) Includes options exercisable for 113,541 shares held by Mr. Doty and 10,030 ordinary shares held by STAK, on behalf of Mr. Doty's wife, Diane M. Doty.
- (10) Includes 18,491,809 shares held by affiliates of Warburg Pincus & Co., or WP. Ms. Weatherman is a Partner of WP and a Managing Director of Warburg Pincus LLC, or WP LLC. All shares indicated as owned by Ms. Weatherman are included because of her affiliation with the Warburg Pincus entities. Ms. Weatherman disclaims all beneficial ownership in such shares. Ms. Weatherman's address is c/o Warburg Pincus LLC, 450 Lexington Avenue, New York, New York 10017.
- (11) Includes 18,491,809 shares held by affiliates of WP and 307,698 ordinary shares held by STAK. Mr. Carney is a Partner of WP and a Managing Director of WP LLC. All shares indicated as owned by Mr. Carney are included because of his affiliation with the Warburg Pincus entities. Mr. Carney disclaims all beneficial ownership in such shares. Mr. Carney is a member of the board of directors of STAK, which board is authorized to act by the affirmative vote of two of its members. All shares indicated as owned by Mr. Carney that are held by STAK are included because of his affiliation with STAK. Mr. Carney disclaims all beneficial ownership in such shares. Mr. Carney's address is c/o Warburg Pincus LLC, 450 Lexington Avenue, New York, New York 10017.
- (12) Includes 3,485,292 shares held by KCH Stockholm AB, or KCH, and 467,797 shares held by Phil Invest ApS. Mr. Tornier wholly owns both KCH and Phil Invest ApS. All shares indicated as owned by Mr. Tornier are included because of his affiliation with these entities.
- (13) Includes 3,383,101 shares held by the Vertical Group, L.P., or The Vertical Group. Mr. Emmitt is a Member and Manager of The Vertical Group GP, LLC, which controls The Vertical Group. All shares indicated as owned by Mr. Emmitt are included because of his affiliation with The Vertical Group. Mr. Emmitt disclaims all beneficial ownership in such shares. Mr. Emmitt's address is c/o The Vertical Group, L.P., 25 DeForest Avenue, Summit, New Jersey 07901.
- (14) Includes 42,208 ordinary shares held by STAK on behalf of Mr. Wallman and options exercisable for 12,500 ordinary shares.
- (15) Reflects shares held by TMG Holdings Coöperatief U.A., or TMG, a Dutch coöperatief. TMG is owned by WP Bermuda, a Bermuda limited partnership, and WP (Bermuda) IX PE One Ltd., or PE One, a Bermuda company. The general partner of WP Bermuda is Warburg Pincus (Bermuda) Private Equity Ltd., or WPPE, a Bermuda company. Each of WP Bermuda, PE One and WPPE is managed by WP LLC. Charles R. Kaye and Joseph P. Landy are the Managing General Partners of WP, and Managing Members and Co-Presidents of WP LLC and may be deemed to control the Warburg Pincus entities. Each of Mr. Kaye and Mr. Landy disclaims beneficial ownership of all shares owned by Warburg Pincus entities. TMG, WP Bermuda, PE One, WPPE, WP LLC and WP are collectively referred to in this Prospectus as Warburg Pincus. The address of the Warburg Pincus entities is 450 Lexington Avenue, New York, New York 10017.
- (16) KCH, a Swedish entity, is wholly owned by Alain Tornier, a member of our board of directors. The address of KCH is Hamilton Advokatbyrå Karlstad AB, Kungsgatan 2A, Box 606, 651 13 Karlstad, Sweden.
- (17) Includes 3,383,101 shares held by Vertical Fund I, L.P., or VFI, a Delaware limited partnership, and Vertical Fund II, L.P., or VFII, a Delaware limited partnership. The Vertical Group L.P., a Delaware limited partnership, is the sole general partner of each of VFI and VFII, and The Vertical Group GP, LLC controls The Vertical Group L.P. The

Table of Contents

sole members and managers of The Vertical Group GP, LLC are Messrs. Tony M. Chou, Richard B. Emmitt, Yue-Teh Jang, Jack W. Lasersohn and John E. Runnells, and these five individuals share voting and investment power over securities held by The Vertical Group, VFI and VFII. The address of The Vertical Group L.P., the Vertical Group GP, LLC, VFI and VFII is 25 DeForest Avenue, Summit, New Jersey 07901.

None of our shareholders has informed us that he or she is affiliated with a registered broker-dealer or is in the business of underwriting securities. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

We describe below transactions and series of similar transactions that have occurred this year or during our last three fiscal years to which we were a party or will be a party in which:

the amounts involved exceeded or will exceed \$120,000; and

a director, executive officer, holder of more than 5% of our ordinary shares or any member of their immediate family had or will have a direct or indirect material interest.

The following persons and entities that participated in the transactions listed in this section were related persons at the time of the transaction:

KCH Stockholm AB and Alain Tornier. KCH Stockholm AB, or KCH, holds more than 5% of our outstanding shares. In addition, KCH is wholly owned by Mr. Tornier, a member of our board of directors.

TMG Holdings Coöperatief U.A., Warburg Pincus (Bermuda) Private Equity IX, L.P., Elizabeth H. Weatherman and Sean D. Carney. TMG Holdings Coöperatief U.A., or TMG, holds more than 5% of our outstanding shares. Our directors Ms. Weatherman and Mr. Carney are Managing Directors of Warburg Pincus LLC, which manages TMG as well as its parent entities Warburg Pincus (Bermuda) Private Equity IX, L.P., or WP Bermuda, WP (Bermuda) IX PE One Ltd. and Warburg Pincus (Bermuda) Private Equity Ltd., or WPPE. Furthermore, Ms. Weatherman and Mr. Carney are Partners of Warburg Pincus & Co., the sole member of WPPE.

Vertical Fund I, L.P., Vertical Fund II, L.P. and Richard B. Emmitt. Vertical Fund I, L.P., or VFI, and Vertical Fund II, L.P., or VFII, together hold more than 5% of our outstanding shares. In addition, Mr. Emmitt, a member of our board of directors, is a Member and Manager of The Vertical Group, L.P., or The Vertical Group, which is the sole general partner of each of VFI and VFII. Mr. Emmitt is also a Member and Manager of The Vertical Group GP, LLC, which controls The Vertical Group.

Douglas W. Kohrs. Mr. Kohrs is our Chief Executive Officer and a member of our board of directors.

Richard F. Wallman. Mr. Wallman is a member of our board of directors.

Private Placements

On February 29, 2008, we issued warrants and notes in a private placement transaction to related parties. The warrants were immediately exercisable and issued at an exercise price of \$16.98 per share as partial consideration for loans in the amounts indicated below. The notes carry a fixed interest rate

Table of Contents

of 8.0% per annum with interest payments accrued semi-annually and mature on February 28, 2013. The related parties involved in the transaction included:

Related party	Number of warrants issued	Amount of note
WP Bermuda	2,211,072 €	24,700,000
VFI and VFII	365,409 €	4,082,000
KCH	313,310 €	3,500,000
Douglas W. Kohrs	50,309 €	562,000
Diane Doty(1)	14,860 €	166,000

(1)

Wife of Michael Doty, our Chief Financial Officer at the time.

On April 3, 2009, we issued immediately exercisable warrants in a private placement to related parties at an exercise price of \$16.98 per share as partial consideration for loans in the amounts indicated below. The notes carry a fixed interest rate of 8.0% per annum with interest payments accrued semi-annually and mature on March 31, 2014. The related parties involved in the transaction included:

Related party	Number of warrants issued	Amount of note
WP Bermuda	890,777 €	11,204,000
KCH	190,813 €	2,400,000
Richard F. and Amy Wallman(1)	20,671 €	260,000
Douglas W. Kohrs	20,512 €	258,000

(1)

Wife of Mr. Wallman.

On March 26, 2010, we sold 13,333 shares to Mr. Wallman for \$300,000. Mr. Wallman's shares were purchased by Stichting Administratiekantoor Tornier, or STAK, on behalf of Mr. Wallman. STAK was established as a foundation under Dutch law to hold our ordinary shares on behalf of certain shareholders.

Warrant Exchange

On May 25, 2010, we completed agreements with 100% of the warrant holders that acquired warrants under the February 29, 2008, and April 3, 2009, private placement agreements listed above. Each warrant holder agreed to exchange their warrants under the February 29, 2008, and April 3, 2009, agreements for Tornier B.V. ordinary shares at an exchange ratio of 0.6133 and 0.6410, respectively. We completed this exchange in order to avoid future variability in our statement of operations from revaluation of the warrants as they were required to be valued at fair value at each reporting period with changes in the fair value reported in current period earnings. In addition, we believed that the number of existing warrants represented potential dilution that may not be desirable to future investors. The exchange ratio used was developed based on the ratio of our estimate of the fair value of each individual warrant to the fair value of each ordinary share. We estimated the fair value of each warrant used in the calculation of the exchange ratio using a Black-Scholes option pricing model.

Acquisitions and Other Corporate Transactions with Related Parties

On July 18, 2006, Tornier N.V., formerly known as TMG B.V., entered into a Securityholders' Agreement with TMG, TMG Partners U.S. LLC, Mr. Kohrs, VFI, VFII, KCH, Mr. Tornier, WP Bermuda and (by subsequent joinder agreements) TMG Partners II LLC, TMG Partners III LLC, Split Rock, STAK, Medtronic and DVO TH, or, collectively, the Securityholders. The agreement grants each

Table of Contents

of the Securityholders a right of first refusal with respect to shares sold by another Securityholder. The Securityholders are further obligated to observe certain limitations on the transfer of their shares, such as tag-along and drag-along rights. These limitations will terminate in the event of an initial public offering approved by our board of directors. In addition, on August 27, 2010, the agreement was amended to allow TMG 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 the Company has agreed to use its reasonable best efforts to cause the TMG designees to be elected. Further, Mr. Kohrs will continue to be entitled to be nominated for election to our board of directors until termination of his employment. The agreement terminates upon the written consent of all parties to the agreement. Mr. Kohrs serves as Manager of the Board of TMG Partners U.S. LLC, and as Managing Member of TMG Partners II LLC and TMG Partners III LLC.

On February 9, 2007, we signed an exclusive, worldwide license and supply agreement with Tepha for its poly-4-hydroxybutyrate polymer for a license fee of \$110,000, plus an additional \$750,000 as consideration for certain research and development. Tepha is further entitled to royalties of up to 5% of sales under these licenses. We paid \$30,000 of minimum royalty payments in April of 2010 to Tepha under the terms of this agreement. VFI and VFII own approximately 20% of Tepha's outstanding common and preferred stock. In addition, Mr. Emmitt serves as a director to Tepha.

At the time of the Axya acquisition, TMG entered into an agreement with KCH, which held mandatorily convertible zero coupon bonds issued by us at the time of the acquisition by the Investor Group. The bonds had a par value of €29,600,000 and were convertible into ordinary shares at a conversion price of €10.0629. In connection with the Axya transaction, TMG agreed that we would either issue to KCH additional mandatorily convertible zero coupon bonds or decrease the conversion price of the zero coupon bonds held by KCH to increase the number of shares issuable upon conversion, if the performance of Axya did not meet certain thresholds. Axya did not meet the performance thresholds within the prescribed time. On October 1, 2009, the mandatorily convertible zero coupon bonds were converted to ordinary shares pursuant to their terms and we issued 2,941,498 ordinary shares to KCH. Rather than adjust the notes or issue additional notes prior to conversion, we also issued KCH an additional 185,698 ordinary shares in satisfaction of the obligation created by TMG.

On January 22, 2008, we signed an agreement with BioSET to develop, commercialize and distribute products incorporating BioSET's F2A synthetic growth factor technology in the field of orthopaedic and podiatric soft tissue repair. As amended on February 10, 2010, this agreement granted us an option to purchase an exclusive, worldwide license for such products in consideration for a payment of \$1 million. We exercised this option on February 10, 2010. Upon FDA approval of certain products, an additional \$2.5 million will become due. BioSET is entitled to royalties of up to 6% for sales of products under this agreement. We have not accrued or paid any royalties under the terms of this agreement. VFI and VFII own approximately 15% of BioSET's outstanding shares and Mr. Emmitt serves on its board of directors.

On June 4, 2010, we issued 43,633 ordinary shares to KCH, having a value equal to €0.7 million. This amount equaled the total amount we owed to Mr. Tornier for past services performed under the terms of his consulting agreement, dated July 31, 2006, based on a per-share price of \$22.50 and a foreign currency exchange rate of 1.3479 U.S. dollars for 1 Euro, the spot conversion rate on March 31, 2010. Mr. Tornier's consulting agreement was terminated effective as of March 31, 2010.

On July 29, 2008, we formed a real estate holding company (SCI Calyx) together with Mr. Tornier. SCI Calyx is owned 51% by us and 49% by Mr. Tornier. SCI Calyx was initially capitalized by a contribution of capital of €10,000 funded 51% by us and 49% by Mr. Tornier. SCI Calyx then acquired

Table of Contents

a combined manufacturing and office facility in Montbonnot, France, for approximately \$6.1 million. The manufacturing and office facility acquired will be used to support the manufacture of certain of our current products and house certain of our operations already located in Montbonnot, France. This real estate purchase was funded through mortgage borrowings of \$4.1 million and \$2.0 million cash borrowed from the two current shareholders of SCI Calyx. The \$2.0 million cash borrowed from the SCI Calyx shareholders originally consisted of a \$1.0 million note due to Mr. Tornier and a \$1.0 million note due to Tornier SAS, which is our wholly owned French operating subsidiary. Both of the notes issued by SCI Calyx bear interest at the three month Euribor rate plus 0.5% and have no stated term. During 2010, SCI Calyx borrowed approximately \$1.4 million from Mr. Tornier in order to fund on-going leasehold improvements necessary to prepare the Montbonnot facility for its intended use. This cash was borrowed under the same terms as the original notes. As of January 2, 2011, SCI Calyx had related-party debt outstanding to Mr. Tornier of \$2.4 million. The SCI Calyx entity is consolidated by us, and the related real estate and liabilities are included in the consolidated balance sheets. On September 3, 2008, Tornier SAS, our French operating subsidiary, entered into a lease agreement with SCI Calyx relating to these facilities. The agreement, which terminates in 2018, provides for an annual rent payment of €440,000, which has subsequently been increased and is currently €748,074 annually. As of January 2, 2011, future minimum payments under this lease were €5.7 million in the aggregate.

Since 2006, Tornier SAS has entered into various lease agreements with entities affiliated with Mr. Tornier or members of his family. On May 30, 2006, Tornier SAS entered into two lease agreements with Mr. Tornier and his sister, Colette Tornier, relating to our facilities in Saint-Ismier, France. The agreements provide for annual rent payments of €104,393 and €28,500, respectively, which have subsequently been increased and are currently €119,362 and €32,587 annually, respectively. On December 29, 2007, Tornier SAS entered into a lease agreement with Animus SCI, relating to our facilities in Montbonnot Saint Martin, France. The agreement provides for an annual rent payment of €252,545, which has subsequently been increased and is currently €288,756 annually. Animus SCI is wholly owned by Mr. Tornier. On December 29, 2007, Tornier SAS entered into a lease agreement with Cymaise SCI, relating to our facilities in Saint-Ismier, France. The agreement provides for an annual rent payment of €315,865, which has subsequently been increased and is currently €361,158 annually. Cymaise SCI is wholly owned by Mr. Tornier and his sister, Colette Tornier. On February 6, 2008, Tornier SAS entered into a lease agreement with Balux SCI, effective as of May 22, 2006, relating to our facilities in Montbonnot Saint Martin, France. The agreement provides for an annual rent payment of €480,000, which has subsequently been increased and is currently €548,828 annually. Balux SCI is wholly owned by Mr. Tornier and his sister, Colette Tornier. Each of the agreements will terminate in 2012. As of January 2, 2011, future minimum payments under these agreements were €1.9 million in the aggregate.

On June 17, 2008, we entered into an exclusive worldwide licensing agreement with C2M Medical, a medical device development company, under which we assumed the rights to certain intellectual property relating to bone anchor technology including the Cinch system. C2M had acquired the technology from Sapphire Medical, Inc., or Sapphire, in April 2007 for a purchase price of \$7.5 million and milestone payments of \$12.5 million, which C2M paid in 2008. In addition, we have committed, and are currently paying, to Sapphire quarterly earn-out fees of 25% of U.S. sales related to Cinch intellectual property for the first three years after launch, an obligation we assumed in the course of our agreement with C2M. The agreement also included an option to acquire C2M Medical. We exercised this option on March 26, 2010, when we purchased 100% of the stock of C2M Medical in exchange for approximately 1.0 million ordinary shares, valued at \$22.50 per share at the time. C2M Medical had been founded and was held in part by TMG, VFI, VFII and Mr. Kohrs. In addition, Mr. Carney, Mr. Emmitt and Mr. Kohrs were members of C2M Medical's board of directors. Prior to our exercise of the option C2M Medical was determined to be a variable interest entity in accordance with U.S. GAAP and we consolidated C2M Medical in our financial statements beginning in June of 2008, the date at which we signed an exclusive technology license with C2M Medical.

Table of Contents

The transaction included:

Related party	Number of shares issued	Total consideration value of shares issued
TMG	504,876	\$ 11,359,714
VFI and VFII	504,876	\$ 11,359,714
Douglas W. Kohrs	15,466	\$ 348,000

Review, Approval or Ratification of Transactions with Related Persons

As provided in our audit committee charter, all related party transactions are to be reviewed and pre-approved by our audit committee. A "related party transaction" is defined to include any transaction or series of transactions exceeding \$120,000 in which we are a participant and any related person has a material interest. Related persons would include our directors, executive officers (and immediate family members of our directors and executive officers) and persons controlling over five percent of our outstanding ordinary shares. In determining whether to approve a related party transaction, the audit committee will generally evaluate the transaction in terms of (i) the benefits to us; (ii) the impact on a director's independence in the event the related person is a director, an immediate family member of a director or an entity in which a director is a partner, shareholder or executive officer; (iii) the availability of other sources for comparable products or services; (iv) the terms and conditions of the transaction; and (v) the terms available to unrelated third parties or to employees generally. The audit committee will then document its findings and conclusions in written minutes. In the event a transaction relates to a member of our audit committee, that member will not participate in the audit committee's deliberations.

Director Independence

The information regarding director independence is disclosed in Item 10 "Directors, Executive Officers, and Corporate Governance Committees of the Board of Directors" of this annual report.

Item 14. Principal Accountant Fees and Services.

The Audit Committee pre-approves all audit and permissible non-audit services to be provided to us by our independent registered public accounting firm prior to commencement of services. The Audit Committee Chairman has the delegated authority to pre-approve such services up to a specified aggregate fee amount. These pre-approval decisions are presented to the full Audit Committee at its next scheduled meeting.

The following table shows the fees that we paid or accrued for audit and other services provided by Ernst & Young for the years 2010 and 2009:

Fees	2010	2009
Audit Fees	\$ 841,226	\$ 907,309
Audit-Related Fees	1,489,071	
Tax Fees	20,393	31,576
All other fees	3,155	128,455

In the above table, "audit fees" are fees for professional services for the audit of our financial statements included in this annual report on Form 10-K, and the review of our financial statements included in registration statements and for services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings or engagements; "audit-related fees" are fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements; "tax fees" are fees for tax compliance,

Table of Contents

tax advice, and tax planning; and "all other fees" are fees for any services not included in the first three categories.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statement Schedules

Financial Statements (See Item 8)

Schedule II Valuation and Qualifying Accounts.

155

Table of Contents

Tornier N.V.
Schedule II-Valuation and Qualifying Accounts
(In thousands)

Description	Balance at beginning of period	Additions Charged to costs & expenses	Deductions		Balance at end of period
			Describe(a)	Describe(b)	
Allowance for Doubtful Accounts (in millions):					
Year ended January 2, 2011	\$ (2,667)	\$ (275)	\$ 307	\$ 116	\$ (2,519)
Year ended December 27, 2009	\$ (2,169)	\$ (601)	\$ 153	\$ (50)	\$ (2,667)
Year ended December 28, 2008	\$ (1,879)	\$ (434)	\$ 119	\$ 25	\$ (2,169)

(a) Uncollectible amounts written off, net of recoveries.

(b) Effect of changes in foreign exchange rates.

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

(b) Exhibit Index

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
3.1	Articles of Association of the Registrant*		
4.1	Registrant's Specimen Certificate for Ordinary Shares.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
4.2	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.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.1	Employment Agreement, dated July 18, 2006, by and between Tornier, Inc. and Douglas W. Kohrs, as amended on August 26, 2010.	Registration Statement on Form S-1, as amended (file number 333-167370)	January 7, 2011
10.2	Employment Agreement, dated June 21, 2010, by and between Tornier, Inc. and Carmen L. Diersen.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.3	Employment Agreement, dated February 5, 2007, by and between Tornier, Inc. and Michael Doty.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.4	Employment Agreement, dated April 28, 2008, by and between Tornier, Inc. and Andrew Joiner.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.5	Employment Agreement, dated August 29, 2008, by and between Tornier, SAS and Stéphan Epinette.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.6	Employment Agreement, dated September 13, 2010, by and between Tornier, Inc. and Kevin Klemz.	Registration Statement on Form S-1, as amended (file number 333-167370)	January 7, 2011
10.7	Separation Agreement, dated February 19, 2010, by and between Tornier, Inc. and Michael Doty.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.8	Letter Agreement, dated December 8, 2008, by and between Tornier B.V. and Richard Wallman.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
10.9	Tornier N.V. Amended and Restated Stock Option Plan.	Registration Statement on Form S-1, as amended (file number 333-167370)	January 18, 2011
10.10	Form of Option Agreement under the Tornier N.V. Stock Option Plan for Directors and Officers.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.11	Retraite Supplémentaire maintained by Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	June 8, 2010
10.12	Asset Purchase Agreement, dated March 5, 2007, by and between DVO Acquisition, Inc. and Tornier B.V.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.13	Merger Agreement, dated January 22, 2007, by and among Nexa Orthopedics, Inc., Tornier US Holdings, Inc. and Nexa Acquisition, Inc.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.14	Agreement and Plan of Merger, dated February 27, 2007, by and among Tornier US Holdings, Inc., Axya Acquisition II, Inc. and Axya Holdings, Inc.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.15	Contribution Agreement, dated March 26, 2010, by and between Tornier B.V., Vertical Fund I, L.P., Vertical Fund II, L.P., TMG Holdings Coöperatief U.A., Stichting Administratiekantoor Tornier, Fred B. Dinger III and Douglas W. Kohrs.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.16	Warrant Agreement, dated February 29, 2008, by and among Tornier B.V. and the former warrant holders party thereto.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.17	EUR 34,500,000 Loan Note Instrument, dated February 29, 2008, issued by Tornier B.V. in favor of the lenders thereto.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
10.18	Warrant Agreement, dated April 3, 2009, by and among Tornier B.V. and the former warrantholders party thereto.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.19	EUR 37,000,000 Loan Note Instrument, dated April 3, 2009, issued by Tornier B.V. in favor of the lenders thereto.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.20	Warrant Exchange Agreement (2008), dated May 25, 2010, by and among Tornier B.V. and the former warrantholders party thereto.(3)	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.21	Warrant Exchange Agreement (2009), dated May 25, 2010, by and among Tornier B.V. and the former warrantholders party thereto.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010
10.22	Commercial leases (two), dated May 30, 2006, by and between Alain Tornier and Colette Tornier and Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.23	Commercial lease, dated December 29, 2007, by and between Animus SCI and Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.24	Commercial lease, dated February 6, 2008, by and between Balux SCI and Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.25	Commercial lease, dated December 29, 2007, by and between Cymaise SCI and Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.26	Commercial lease, dated September 3, 2008, by and between SCI Calyx and Tornier SAS.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.27	Commercial lease, dated December 23, 2008, by and between Seamus Geaney and Tornier Orthopedics Ireland Limited.	Registration Statement on Form S-1, as amended (file number 333-167370)	July 15, 2010

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
10.28	Securityholders' Agreement, dated July 18, 2006, by and among the parties listed on Schedule I thereto, KCH Stockholm AB, Alain Tornier, Warburg Pincus (Bermuda) Private Equity IX, L.P., TMG B.V. (predecessor to Tornier B.V.).	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.29	Joinder Agreement, dated March 30, 2007, by and between Tornier B.V. and DVO Extremity Solutions, LLC.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.30	Joinder Agreement, dated September 24, 2007, by and between Tornier B.V. and TMG Partners II LLC.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.31	Joinder Agreement, dated October 27, 2008, by and between Tornier B.V. and TMG Partners III LLC.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.32	Joinder Agreement, dated May 11, 2009, by and between Tornier B.V. and Split Rock Partners, L.P.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.33	Joinder Agreement, dated April 2008, by and between Tornier B.V. and Stichting Administratiekantoer Tornier.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.34	Joinder Agreement, dated May 25, 2010, by and between Tornier B.V. and Medtronic Bakken Research Center B.V.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.35	Quality Assurance Agreement, dated April 1, 1998, by and between CeramTec AG and Tornier SA.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.36	By-Laws of SCI Calyx.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
10.37	Amendment to the Securityholders' Agreement, dated August 27, 2010, by and among the securityholders on Schedule I thereto and Tornier B.V.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.38	Subscription Agreement, dated July 18, 2006, by and between TMG B.V. and KCH Stockholm AB.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.39	Conversion Notice, dated October 1, 2009, by Tornier B.V. addressed to KCH Stockholm AB.	Registration Statement on Form S-1, as amended (file number 333-167370)	August 11, 2010
10.40	Form of Indemnification Agreement.	Registration Statement on Form S-1, as amended (file number 333-167370)	September 14, 2010
10.41	Tornier N.V. 2010 Stock Incentive Plan.	Registration Statement on Form S-1, as amended (file number 333-167370)	October 4, 2010
10.42	Tornier N.V. 2010 Employee Stock Purchase Plan.	Registration Statement on Form S-1, as amended (file number 333-167370)	January 18, 2011
21.1	Subsidiaries of the Registrant.*		
23.1	Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm.*		
31.1	Certification pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*		
31.2	Certification pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*		
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*		

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Exhibit Number	Description of Document	Incorporated by Reference Herein Form	Date
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*		

*

Filed herewith.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 11, 2011

Tornier N.V.

By: /s/ DOUGLAS W. KOHRS

Douglas W. Kohrs

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this annual report has been signed below by the following persons on behalf of the registrant and in the capacity and on the dates indicated.

Signature	Title	Date
<u>/s/ DOUGLAS W. KOHRS</u> Douglas W. Kohrs	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2011
<u>/s/ CARMEN L. DIERSEN</u> Carmen L. Diersen	Global Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2011
<u>/s/ SEAN D. CARNEY</u> Sean D. Carney	Director	March 11, 2011
<u>/s/ RICHARD B. EMMITT</u> Richard B. Emmitt	Director	March 11, 2011
<u>/s/ KEVIN C. O'BOYLE</u> Kevin C. O'Boyle	Director	March 11, 2011
<u>/s/ ALAIN TORNIER</u> Alain Tornier	Director	March 11, 2011
<u>/s/ PASCAL E.R. GIRIN</u> Pascal E.R. Girin	Director	March 11, 2011

Edgar Filing: Tornier N.V. - Form 10-K

Table of Contents

Signature	Title	Date
<div>/s/ RICHARD F. WALLMAN</div> <div>Richard F. Wallman</div>	Director	March 11, 2011
<div>/s/ ELIZABETH H. WEATHERMAN</div> <div>Elizabeth H. Weatherman</div>	Director	March 11, 2011
164		