Tornier N.V.
Form 10-Q
November 09, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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: 1-35065

TORNIER N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	**98-0509600**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
Fred. Roeskestraat 123	
1076 EE Amsterdam, The Netherlands	**None**
(Address of Principal Executive Offices)	**(Zip Code)**

(+ 31) 20 675 4002

(Registrant s Telephone Number, Including Area Code)

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. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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.) x Yes ¨ No

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

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

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

As of November 5, 2012, there were 41,724,712 ordinary shares outstanding.

Table of Contents

TORNIER N.V.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

TABLE OF CONTENTS

On January 28, 2011, Tornier B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) changed its legal form by converting to Tornier N.V., a public company with limited liability (*naamloze vennootschap*). This is referred to as the conversion in this report.

References to Tornier, Company, we, our or us in this report refer to Tornier B.V. and its subsidiaries prior to the conversion and to Tornier and its subsidiaries upon and after the conversion, unless the context otherwise requires.

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

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact included in this 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, operating results and business. We have identified some of these forward-looking statements with words like believe, may, will, should, could, expect, intend, plan, predict, anticipate, estimate or continue, other words a meaning and the use of future dates. These forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially from those matters expressed or implied by our forward-looking statements. Forward-looking statements (including oral representations) are only predictions or statements of current plans and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including, among other things, risks associated with:

our history of operating losses and negative cash flow;

our recent acquisition of OrthoHelix Surgical Designs, Inc., and risks related thereto, including our inability to integrate successfully our commercial organizations, including in particular our distribution and sales representative arrangements, and our failure to realize the anticipated benefits and synergies to our business and operating results;

our facilities consolidation initiative and its effect on our business and operating results;

continuing weakness in the global economy, which may be exacerbated by austerity measures anticipated to be taken by several countries and which could reduce the availability or affordability of private insurance or may affect patient decision to undergo elective procedures, and could otherwise adversely affect our business and operating results;

deriving a significant portion of our revenues from operations in certain geographic markets that are subject to political, economic and social instability and risks and uncertainties involved in launching our products in certain new geographic markets, including in particular Japan and China;

disruption and turmoil in global credit and financial markets, which may be exacerbated by the inability of certain countries to continue to service their sovereign debt obligations;

fluctuations in foreign currency exchange rates;

changes in our senior management, including our recent Chief Financial Officer change;

our new credit agreement, senior secured term loans and revolving credit facility;

our reliance on our independent sales agencies and distributors to sell our products and the effect on our business and operating results of agency and distributor changes or transitions to direct selling models in certain geographies, including most recently in Belgium and Luxembourg;

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

not successfully competing against our existing or potential competitors;

the reliance of our business plan on certain market assumptions;

our reliance on sales of our shoulder products, which generate a significant portion of our revenue;

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

our plans to bring the manufacturing of certain of our products in-house and possible disruptions we may experience in connection with such transition;

our plans to increase our gross margins by taking certain actions designed to do so;

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

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

the incurrence of significant expenditures of resources to maintain relatively high levels of inventory, which could reduce our cash flows and increase the risk of inventory obsolescence, which could harm our operating results;

our inability to access our revolving credit facility or raise capital when needed, which could force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs;

restrictive affirmative financial and other covenants in our new credit agreement that may limit our operating flexibility;

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 operating results;

Table of Contents

our clinical trials and their results and our reliance on third parties to conduct them;

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

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

the use, misuse or off-label use of our products that may harm our image in the marketplace or result in injuries that may lead to product liability suits, which could be costly to our business or result in governmental sanctions;

healthcare reform legislation and its future implementation, possible additional legislation, regulation and other governmental pressure in the United States and globally, which may affect utilization, pricing, reimbursement, taxation and rebate policies of governmental agencies and private payors, which could have an adverse effect on our business, financial condition or operating results; and

pending and future litigation.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see the information under the heading Part II Item 1A. Risk Factors of this report. The risks and uncertainties described above and under the heading Part I Item 1A Risk Factors in this report are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our future annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

Table of Contents

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TORNIER N.V. AND SUBSIDIARIES

Consolidated Balance Sheets

(U.S. dollars in thousands, except share and per share amounts)

	September 30, 2012 (unaudited)	January 1, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 58,499	$ 54,706
Accounts receivable (net of allowance of $4,695 and $2,486, respectively)	42,704	45,908
Inventories	81,368	79,883
Deferred income taxes	620	620
Prepaid taxes	13,282	12,417
Prepaid expenses	3,428	2,225
Other current assets	4,473	3,113
Total current assets	204,374	198,872
Instruments, net	48,528	49,347
Property, plant and equipment, net	35,893	33,353
Goodwill	132,459	130,544
Intangible assets, net	93,341	97,665
Deferred income taxes	69	69
Other assets	2,079	1,850
Total assets	$ 516,743	$ 511,700
Liabilities and shareholders equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	$ 25,966	$ 18,011
Accounts payable	10,044	12,020
Accrued liabilities	38,339	34,445
Income taxes payable	590	917
Deferred income taxes	45	81
Total current liabilities	74,984	65,474
Other long-term debt	21,084	21,900
Deferred income taxes	18,471	16,966
Other non-current liabilities	5,545	5,900
Total liabilities	120,084	110,240
Shareholders equity:		
Ordinary shares, 0.03 par value; authorized 175,000,000; issued and outstanding 39,747,793 and 39,270,029 at September 30, 2012 and January 1, 2012, respectively	1,579	1,560
Additional paid-in capital	620,746	608,772
Accumulated deficit	(230,929)	(213,988)
Accumulated other comprehensive income	5,263	5,116

Total shareholders equity	396,659	401,460
Total liabilities and shareholders equity	$ 516,743	$ 511,700

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

Table of Contents

TORNIER N.V. AND SUBSIDIARIES

Consolidated Statements of Operations

(U.S. dollars in thousands, except share and per share amounts)

	Three months ended		Nine months ended	
	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
	(unaudited)		(unaudited)	
Revenue	$ 58,015	$ 57,556	$ 198,487	$ 192,149
Cost of goods sold	15,730	16,650	54,944	54,708
Gross profit	42,285	40,906	143,543	137,441
Operating expenses:				
Selling, general and administrative	38,524	37,937	124,157	119,895
Research and development	5,260	4,309	16,329	14,608
Amortization of intangible assets	2,730	2,741	8,013	8,448
Special charges	6,503	56	9,413	188
Total operating expenses	53,017	45,043	157,912	143,139
Operating loss	(10,732)	(4,137)	(14,369)	(5,698)
Other income (expense):				
Interest income	70	145	304	415
Interest expense	(481)	(524)	(1,430)	(3,761)
Foreign currency transaction loss	(326)	(228)	(195)	(81)
Loss on extinguishment of debt				(29,475)
Other non-operating income	56	993	54	1,009
Loss before income taxes	(11,413)	(3,751)	(15,636)	(37,591)
Income tax (expense) benefit	(268)	2,114	(1,305)	9,116
Consolidated net loss	(11,681)	(1,637)	(16,941)	(28,475)
Net loss per share:				
Basic and diluted	$ (0.29)	$ (0.04)	$ (0.43)	$ (0.75)
Weighted average shares outstanding:				
Basic and diluted	39,708	39,150	39,537	37,882

TORNIER N.V. AND SUBSIDIARIES

Consolidated Statements of Comprehensive (Loss) Income

(in thousands)

	Three months ended		Nine months ended	
	September 30, 2012	October 2, 2011	September 30, 2012	October 2, 2011
	(unaudited)			
Consolidated net loss	$ (11,681)	$ (1,637)	$ (16,941)	$ (28,475)
Foreign currency translation adjustments	6,395	(16,753)	147	(278)

Comprehensive (loss)	$ (5,286)	$ (18,390)	$ (16,794)	$ (28,753)

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

Table of Contents

TORNIER N.V. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(U.S. dollars in thousands)

	Nine months ended	
	September 30, 2012	October 2, 2011
	(unaudited)	
Cash flows from operating activities:		
Consolidated net loss	$ (16,941)	$ (28,475)
Adjustments to reconcile consolidated net loss to cash provided by operating activities:		
Depreciation and amortization	21,398	21,038
Impairment of fixed assets	1,028	
Lease termination costs	731	
Non-cash foreign currency (loss) income	(217)	387
Deferred income taxes	(147)	(8,993)
Share-based compensation	5,108	4,741
Non-cash interest expense and discount amortization		2,040
Inventory obsolescence	2,913	3,814
Loss on extinguishment of debt		29,475
Incentive related to new facility lease	703	
Other non-cash items affecting earnings	1,441	(347)
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable	4,533	(534)
Inventories	(3,474)	(11,015)
Accounts payable and accruals	(3,429)	(3,449)
Other current assets and liabilities	(1,317)	3,556
Other non-current assets and liabilities	(1,194)	(1,277)
Net cash provided by operating activities	11,136	10,961
Cash flows from investing activities:		
Acquisition-related cash payments	(2,246)	
Purchases of intangible assets	(1,410)	(2,053)
Additions of instruments	(9,245)	(15,042)
Property, plant and equipment lease incentive	(1,020)	
Purchases of property, plant and equipment	(6,866)	(3,772)
Net cash used in investing activities	(20,787)	(20,867)
Cash flows from financing activities:		
Change in short-term debt	9,350	(8,185)
Repayments of long-term debt	(8,233)	(6,458)
Repayments of notes payable		(116,108)
Proceeds from issuance of long-term debt	5,172	4,751
Deferred financing costs		(2,731)
Issuance of ordinary shares from stock option exercises	6,939	2,958
Other issuance of ordinary shares	169	168,257
Net cash provided by financing activities	13,397	42,484
Effect of exchange rate changes on cash and cash equivalents	47	(1,568)
Increase in cash and cash equivalents	3,793	31,010
Cash and cash equivalents:		
Beginning of period	54,706	24,838

End of period	$ 58,499	$ 55,848
Non-cash investing and financing activities:		
Fixed assets acquired pursuant to capital lease	$ 359	$ 646

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

Table of Contents

TORNIER N.V. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(unaudited)

1. Business Description

Tornier N.V. (Tornier 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. The Company refers to these surgeons as extremity specialists. The Company 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. The Company currently sells over 110 product lines in over 35 countries, including products acquired as a result of the recent acquisition of OrthoHelix Surgical Designs, Inc. (OrthoHelix) subsequent to September 30, 2012. See Note 15.

On January 28, 2011, the Company executed a 3-to-1 reverse stock split of the Company s ordinary shares. All share and per share amounts for all periods presented in these condensed consolidated financial statements reflect this 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*).

All amounts are presented in U.S. Dollar ($), except where expressly stated as being in other currencies, e.g. Euros ( ).

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 $149.2 million (after underwriters discounts and commissions of approximately $10.8 million and additional offering related costs of $6.2 million). Net proceeds have been and will continue to 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 additional net proceeds of approximately $12.8 million (after underwriters discounts and commissions of approximately $0.9 million).

2. Summary of Significant Accounting Policies

Consolidation

The unaudited consolidated financial statements include the accounts of Tornier N.V. and all of its wholly and majority owned subsidiaries. In consolidation, all material intercompany accounts and transactions are eliminated.

The unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) for interim financial information and the instructions to quarterly report on Form 10-Q and Rule 10-01 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) have been condensed or omitted pursuant to these rules and regulations. Accordingly, these unaudited consolidated interim financial statements should be read in conjunction with the Company s consolidated financial statements and related notes included in the Company s annual report on Form 10-K for the year ended January 1, 2012, as filed with the U.S. Securities and Exchange Commission (SEC).

Reclassifications

Certain amounts reported in previous periods have been reclassified to conform with the current period presentation. The Company combined sales and marketing expenses and general and administrative expenses on the consolidated statement of operations. These combined expenses are now referred to as selling, general and administrative expenses.

Basis of Presentation

The Company s fiscal quarters are generally determined on a 13-week basis and always end on a Sunday. As a result, the Company s fiscal year is generally 364 days. Fiscal year-end periods end on the Sunday nearest to December 31. Every few years, it is necessary to add an extra week to a quarter to make it a 14-week period in order to have the year-end fall on the Sunday nearest to December 31. The first, second and third quarters of 2012 and 2011 each consisted of 13 weeks.

Table of Contents

In the opinion of the Company s management, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of normal recurring accruals, necessary for the fair presentation of the Company s interim results. The results of operations for any interim period are not indicative of results for the full fiscal year.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05, *Comprehensive Income (Topic 220), Presentation of Comprehensive Income*. The guidance requires an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. Companies will no longer be permitted to present components of other comprehensive income solely in the statements of stockholders equity. The Company adopted ASU 2011-05 beginning in the quarter ended April 1, 2012 and has made the appropriate disclosures in the consolidated financial statements.

In September 2011, the FASB issued ASU 2011-08, *Goodwill and Other (ASC Topic 350), Testing Goodwill for Impairment*, which simplified the requirements related to the annual goodwill impairment test. Companies now have the option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the assessment indicates that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company no longer has to perform the two-step impairment test. ASU 2011-08 was effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted this guidance beginning in the first quarter of 2012. The impact of adoption did not have a material impact on the Company s consolidated financial position or operating results.

Although there are several other new accounting pronouncements issued or proposed by the FASB, which the Company has adopted or will adopt, as applicable, the Company does not believe any of these accounting pronouncements has had or will have a material impact on the Company s consolidated financial position or operating results.

3. Fair Value of Financial Instruments

The Company applies Accounting Standards Codification (ASC) Topic 820, which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. The Company measures certain assets and liabilities at fair value on a recurring or non-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

A summary of the financial assets and liabilities that are measured at fair value on a recurring basis at September 30, 2012 and January 1, 2012 are as follows:

	September 30, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$ 58,499	$ 58,499	$	$
Earn-out liability	(793)			(793)
Derivative liability	(87)		(87)	
Total, net	$ 57,619	$ 58,499	$ (87)	$ (793)

	January 1, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$ 54,706	$ 54,706	$	$
Total, net	$ 54,706	$ 54,706	$	$

As of September 30, 2012, the Company had a derivative liability with recurring Level 2 fair value measurements. The derivative is a foreign exchange forward contract and its fair value is based on pricing for similar recently executed transactions. The amount of loss recognized in foreign exchange loss for the nine months ended September 30, 2012 related to this derivative is approximately $0.1 million. Included in Level 3 fair value measurements is a $0.8 million earn-out liability as of September 30, 2012 related to the acquisition of the Company s exclusive distributor in Belgium and Luxembourg. The current portion of the liability is recorded in other current liabilities on the consolidated balance sheet. The long-term portion of the earn-out liability is included in other noncurrent liabilities on the consolidated balance sheet. The earn-out liability is carried at fair value and was determined based on a discounted cash flow analysis that included a probability assessment and a discount rate, both of which are considered significant unobservable inputs. To the extent that these assumptions were to change, the fair value of the earn-out liability could change significantly. This liability did not exist prior to the acquisition transaction on June 1, 2012. For the nine months ended September 30, 2012, the Company had recognized less than $0.1 million on the mark-to-market of the earn-out liability within interest expense on the consolidated statement of operations. There were no transfers into or out of Level 3 fair value measurements in the period.

The Company also has some assets and liabilities that are measured at fair value on a non-recurring basis. The Company reviews the carrying amount of its long-lived assets other than goodwill for potential impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. During the nine months ended September 30, 2012, the Company initiated a facilities consolidation initiative that included the planned closure and consolidation of certain facilities in France, Ireland and the U.S., which resulted in the recognition of a $1.0 million impairment charge to write down certain fixed assets to their estimated fair values. The fair value calculations were performed using a cost-to-sell analysis and are considered Level 2 fair value measurements as the key inputs into the calculations included estimated market values of the facilities, which are considered indirect observable inputs. In addition, the Company has recorded $0.7 million of lease termination costs for the nine months ended September 30, 2012 related to the facilities consolidation initiative. The termination costs were determined using a discounted cash flow analysis that included a discount rate assumption, which is based on the credit adjusted risk free interest rate input, and an assumption related to the timing and amount of sublease income, both of which are considered unobservable inputs and thus considered a Level 3 fair value measurement.

Based on the Company s existing mix (interest rates and terms) of fixed rate debt, the overall fair value of its long-term debt approximates the carrying value.

4. Inventories

Inventory balances consist of the following (in thousands):

	September 30, 2012	January 1, 2012
Raw materials	$ 5,765	$ 5,986
Work-in-process	5,107	4,766
Finished goods	70,496	69,131
Total	$ 81,368	$ 79,883

Table of Contents

5. Property, Plant and Equipment

Property, plant and equipment balances consist of the following (in thousands):

	September 30, 2012	January 1, 2012
Land	$ 2,087	$ 2,138
Building and improvements	12,017	12,501
Machinery and equipment	22,438	20,335
Furniture, fixtures and office equipment	26,716	24,255
Software	4,498	4,110
Construction in progress	2,463	
Property, plant, and equipment, gross	70,219	63,339
Accumulated depreciation	(34,326)	(29,986)
Property, plant and equipment, net	$ 35,893	$ 33,353

As a result of the facilities consolidation initiative, the Company recorded several fixed asset impairments during fiscal 2012 related to the Company s facilities in St. Ismier, France, Dunmanway, Ireland, and Stafford, Texas in the aggregate amount of $1.0 million for the nine months ended September 30, 2012. These changes are reflected in related fixed asset categories above. These impairments were recorded in special charges, a component of operating expenses, in the consolidated statements of operations for the three and nine months ended September 30, 2012. See Note 13 for further description of the facilities consolidation initiative.

6. Instruments

Instruments included in long-term assets on the consolidated balance sheets consist of the following (in thousands):

	September 30, 2012	January 1, 2012
Instruments	$ 78,736	$ 72,971
Instruments in process	18,371	18,024
Accumulated depreciation	(48,579)	(41,648)
Instruments, net	$ 48,528	$ 49,347

The Company recorded an impairment of $0.3 million for the nine months ended September 30, 2012 related to instrument set components that were scrapped as a result of a revision to an existing product line.

7. Goodwill and Other Intangible Assets

The following table summarizes the changes in the carrying amount of goodwill (in thousands):

Balance at January 1, 2012	$ 130,544
Acquisition related payments	1,943
Foreign currency translation	(28)
Balance at September 30, 2012	$ 132,459

7

Table of Contents

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

	Gross value	Accumulated amortization	Net value
Balances at September 30, 2012			
Intangible assets subject to amortization:			
Developed technology	$ 75,082	$ (33,394)	$ 41,688
Customer relationships	63,039	(24,877)	38,162
Licenses	5,546	(2,699)	2,847
Other	2,379	(1,328)	1,051
Intangible assets not subject to amortization:			
Trade name	9,593		9,593
Total	$ 155,639	$ (62,298)	$ 93,341

	Gross value	Accumulated amortization	Net value
Balances at January 1, 2012			
Intangible assets subject to amortization:			
Developed technology	$ 75,106	$ (29,313)	$ 45,793
Customer relationships	60,399	(21,821)	38,578
Licenses	4,882	(2,061)	2,821
Other	1,930	(1,056)	874
Intangible assets not subject to amortization:			
Trade name	9,599		9,599
Total	$ 151,916	$ (54,251)	$ 97,665

Estimated annual amortization expense for fiscal years ending 2012 through 2016 is as follows (in thousands):

	Amortization expense
2012	$ 10,757
2013	10,653
2014	10,414
2015	10,377
2016	9,792

During the nine months ended September 30, 2012, the Company acquired its exclusive distributor in Belgium and Luxembourg for $3.5 million, which included a $1.0 million earn-out. The preliminary purchase accounting for this transaction resulted in an increase in intangible assets of $3.0 million and goodwill of $0.8 million for the nine months ended September 30, 2012.

8. Other Long-Term Debt

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

	September 30, 2012	January 1, 2012
Lines of credit and overdraft arrangements	$ 18,138	$ 9,989

Mortgages	4,972	5,508
Other term debt	21,790	22,262
Shareholder debt	2,150	2,152
Total debt	47,050	39,911
Less current portion	(25,966)	(18,011)
Long-term debt	$ 21,084	$ 21,900

The Company s European subsidiaries had established unsecured bank overdraft arrangements which allowed for available credit totaling $24.5 million and $23.8 million at September 30, 2012 and January 1, 2012, respectively. Borrowings under these overdraft arrangements were $16.6 million and $10.0 million at September 30, 2012 and January 1, 2012, respectively. Borrowings under these overdraft arrangements had variable annual interest rates based on the Euro Overnight Index Average plus 1.3% or the three-month Euro Index plus 0.5% to 3.0%.

Table of Contents

The Company s U.S. operating subsidiary had a $10.0 million secured line of credit at September 30, 2012 and January 1, 2012. This line of credit was scheduled to expire on November 1, 2012 and was secured by working capital and equipment. There was $1.5 million outstanding under this line at September 30, 2012. There was no balance outstanding as of January 1, 2012. Borrowings under the line of credit bore annual interest at 30-day LIBOR plus 2.25%, with a floor interest rate of 5%. This line contained customary affirmative and negative covenants and events of default. As of September 30, 2012, the Company s U.S. operating subsidiary was subject to a covenant to maintain no less than $55 million of tangible net worth. As of September 30, 2012, the Company was also subject to a covenant to maintain a maximum debt to tangible net worth ratio of 1.00 and a debt service coverage ratio of no less than 1.25. The covenants relate to the U.S. operating subsidiary s ratios only. The Company was in compliance with all covenants as of September 30, 2012.

The Company s international subsidiaries had other long-term secured and unsecured notes totaling $21.8 million and $22.3 million at September 30, 2012 and January 1, 2012, respectively, with initial maturities ranging from one to 10 years. A portion of these notes had fixed annual interest rates that ranged from 2.8% to 7.6%. The remaining notes carried a variable annual interest rate based on LIBOR, plus 1.2%, or the three-month Euro Index plus 0.3% to 1.5%.

The Company has a mortgage secured by the Company s U.S. operating subsidiary s facility in Stafford, Texas. This mortgage had an outstanding amount of $1.2 million at both September 30, 2012 and January 1, 2012. This mortgage bears a variable annual interest rate of LIBOR plus 2%.

The Company also has a mortgage secured by an office building in Grenoble, France. This mortgage had an outstanding balance of $3.8 million at September 30, 2012 and $4.3 million at January 1, 2012. This mortgage bears a fixed annual interest rate of 4.9%.

In 2008, one of the Company s 51%-owned and consolidated subsidiaries borrowed $2.5 million from a member of the Company s 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 manufacturing facility. Annual interest on the debt is variable based on three-month Euro Index plus 0.5%. The non-controlling interest in this subsidiary is deemed immaterial to the consolidated financial statements. The current outstanding balance on the loan is $2.2 million.

On October 4, 2012, the Company, and its U.S. operating subsidiary, Tornier, Inc. (Tornier USA), entered into a credit agreement with a group of 4 banks to provide both term and revolving credit. The borrowings under the credit agreement were used at the closing of the acquisition of OrthoHelix described in Note 15 to pay the consideration for such acquisition, and such fees, costs and expenses incurred in connection with the acquisition, fees and expenses associated with the new credit agreement and to repay prior existing indebtedness of the Company and its subsidiaries. See Note 15 for further details.

9. Notes Payable and Warrants to Issue Ordinary Shares

In April 2009, the Company issued notes payable in the aggregate amount of 37 million (approximately $49.3 million) to a group of investors that included then existing shareholders, new investors and management of the Company. The notes carried a fixed annual interest rate of 8.0% with interest payments accrued in kind semi-annually. The notes were set to mature in March 2014. In connection with the note agreement, the Company also issued warrants to purchase an aggregate of 2.9 million ordinary shares at an exercise price of $16.98 per share. 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 was being amortized as additional interest expense over the life of the notes. The Company executed agreements in May 2010 where 100% of the warrants were exchanged for ordinary shares.

In February 2008, the Company issued notes payable in the aggregate amount of 34.5 million (approximately $52.4 million) to a group of investors that included then existing shareholders and management of the Company. The notes carried a fixed annual interest rate of 8.0% with interest payments accrued in-kind. The notes were set to mature on February 28, 2013. Also, in connection with the 2008 note agreement, the Company issued warrants to purchase an aggregate of 3.1 million ordinary shares at a price of $16.98 per share. The Company had recorded the warrants as liabilities with an offsetting debt discount recorded as a reduction of the carrying value of the notes. The debt discount was being amortized as additional interest expense over the life of the notes. The Company executed agreements in May 2010 where 100% of the warrants were exchanged for ordinary shares.

In February 2011, the Company used approximately $116.1 million (86.4 million) of the net proceeds from its initial public offering to repay all of the outstanding indebtedness under the notes payable, including accrued interest thereon. At the time of repayment, the Company recognized a loss on debt extinguishment of $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.

9

Table of Contents

Notes payable balances prior to the repayment in February of 2011 were as follows:

	February 14, 2011 (Time of Repayment)	January 2, 2011
Gross notes payable	$ 116,109	$ 114,357
Discount to notes payable	(29,352)	(30,096)
Net notes payable	$ 86,757	$ 84,261

10. Share-Based Compensation

Share-based awards are granted under the Tornier N.V. 2010 Incentive Plan, as amended. This plan allows for the issuance of up to a maximum of 7.7 million ordinary shares in connection with the grant of share-based awards, including stock options, stock grants, stock appreciation rights and other types of awards as deemed appropriate. To date, only options to purchase ordinary shares (options) and stock grants in the form of restricted stock units (RSUs) have been awarded under the plan. Both types of awards generally have graded vesting periods of four years and the options expire ten years after the grant date. 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 awards on a straight-line basis over the vesting period. Share-based compensation expense is included in cost of goods sold, selling, general and administrative expense, and research and development expense on the consolidated statements of operations.

Below is a summary of the allocation of share-based compensation (in thousands):

	Three months ended		Nine months ended	
	September 30, 2012	October 2, 2011 (unaudited)	September 30, 2012	October 2, 2011 (unaudited)
Cost of goods sold	$ 206	$ 199	$ 656	$ 586
Selling, general and administrative	1,366	1,492	4,139	3,784
Research and development	141	140	313	371
Total	$ 1,713	$ 1,831	$ 5,108	$ 4,741

Table of Contents

During the nine months ended September 30, 2012, the Company granted options to purchase an aggregate of 0.5 million ordinary shares to employees at a weighted average exercise price of $18.73 per share and a weighted average fair value of $8.70 per share. During the nine months ended October 2, 2011, the Company granted options to purchase an aggregate of 0.6 million ordinary shares to employees at a weighted average exercise price of $24.35 per share and a weighted average fair value of $11.90 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:

	Nine months ended September 30, 2012
Risk-free interest rate	1.0%
Expected life in years	6.1
Expected volatility	48.2%
Expected dividend yield	0.0%

During the nine months ended September 30, 2012 and October 2, 2011, the Company granted 0.3 million and 0.2 million restricted stock units, respectively, to employees with a weighted average fair value of $18.80 per share and $25.16 per share, respectively.

11. Income Taxes

Our effective tax rate for the nine months ended September 30, 2012 and nine months ended October 2, 2011 was 8% and 24%, respectively. The Company operates in multiple income tax jurisdictions both inside and outside the United States. Income tax authorities in these jurisdictions regularly perform audits of the Company s income tax filings. Accordingly, management must determine the appropriate allocation of income to each of these jurisdictions based on current interpretations of complex income tax regulations. Income tax audits associated with the allocation of this income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period of time to resolve and may result in significant income tax adjustments if changes to the income allocation are required between jurisdictions with different income tax rates.

During the nine months ended September 30, 2012, the Company recognized $1.3 million of income tax expense on pre-tax losses of $15.6 million. During the nine months ended October 2, 2011, the Company recognized $9.1 million of income tax benefit on pre-tax losses of $37.6 million. Of the $9.1 million income tax benefit, $7.5 million related to the $29.5 million loss on extinguishment of debt previously discussed. This benefit was the result of reversing the remaining deferred tax liability related to the unamortized debt discount on the Company s notes payable at the time of repayment. Offsetting this deferred tax benefit are estimated income tax expenses primarily related to the Company s French subsidiaries. Given the Company s history of operating losses, the Company does not generally recognize a provision for income taxes in the United States and certain of the Company s European sales offices.

12. Capital Stock and Earnings Per Share

The Company had 39.7 million and 39.3 million ordinary shares issued and outstanding as of September 30, 2012 and January 1, 2012, respectively.

The Company had options to purchase ordinary shares and restricted stock units outstanding of 4.3 million and 4.4 million ordinary shares at September 30, 2012 and January 1, 2012, respectively. None of the options or restricted stock units were included in diluted earnings per share for the nine months ended September 30, 2012 and January 1, 2012, respectively, because the Company recorded a net loss in all periods, and therefore, including these instruments would be anti-dilutive.

13. Special Charges

The Company recognizes expense resulting directly from business combinations, restructuring initiatives, certain termination benefits and other items as special charges in its consolidated statement of operations.

On April 13, 2012, the Company announced a facilities consolidation initiative, stating that it planned to consolidate several of its facilities to drive operational productivity and to reduce annual operating expenses by $2.3 to $2.8 million beginning in 2013. The Company s facilities consolidation initiative includes the closure and relocation of its distribution operations in Stafford, Texas to Minnesota. The Company is consolidating these operations with its U.S.-based marketing, training, regulatory, clinical, supply chain, and corporate functions into a single

leased site in the Minneapolis, Minnesota area. European facilities consolidated into nearby Company sites include those in St. Ismier, France and Dunmanway, Ireland.

Table of Contents

The Company estimates it will incur restructuring charges of approximately $6.0 to $7.0 million related to this initiative, substantially all of which will be incurred in 2012.

Charges incurred in connection with the facilities consolidation initiative during the nine months ended September 30, 2012 are presented in the following table (in thousands). All of the following amounts were recognized within special charges in the Company s consolidated statements of operations.

	Nine months ended September 30, 2012
Employee termination benefits	$ 892
Impairment charges related to fixed assets	1,025
Moving, professional fees and other initiative-related expenses	3,337
Total facilities consolidation expenses	$ 5,254

The $0.9 million of employee termination benefits includes severance and retention related to employees impacted by the facilities consolidation initiative in the U.S. The Company estimates that 60 employees will be affected as a result of the closure of the Stafford, Texas facility and related plans. As of September 30, 2012, approximately 33 employees have been impacted. The $1.0 million of impairment charges related to fixed assets include charges for closing the impacted facilities in the U.S., France and Ireland. The $3.3 million of moving, professional fees and other initiative-related expenses include moving and transportation expenses, lease termination costs, professional fees and other expenses that were incurred to execute the facilities consolidation initiative.

Included in accrued liabilities on the consolidated balance sheet is an accrual related to the facilities consolidation initiative. Activity in the facilities consolidation accrual is presented in the following table (in thousands):

Facility consolidation accrual balance as of January 2, 2012	$
Charges:	
Employee termination benefits	892
Moving, professional fees and other initiative-related expenses	3,337
Total charges	$ 4,229
Payments:	
Employee termination benefits	$ (268)
Moving, professional fees and other initiative-related expenses	(2,326)
Total payments	$ (2,594)
Facilities consolidation accrual balance as of September 30, 2012	$ 1,635

The Company anticipates that substantially all of this accrual will be paid in 2012.

Also included in special charges on the consolidated statement of operations for the nine months ended September 30, 2012 is $0.4 of severance related to the Company s former Chief Financial Officer, $2.0 million of bad debt expense related to the termination of a distributor and general economic conditions in Italy, $0.8 million of termination costs related to certain strategic business decisions made related to the Company s U.S. and international distribution channels and $1.0 million of acquisition and integration costs related to the Company s acquisition of OrthoHelix and our exclusive distributor in Belgium and Luxembourg. Included in special charges on the consolidated statement of operations for the nine months ended October 2, 2011 are $0.2 million of charges related to the closure of the Company s Beverly, Massachusetts facility.

14. Litigation

On October 25, 2007, two of the Company s former sales agents filed a complaint in the U.S. District Court for the Southern District of Illinois, alleging that the Company had breached their agency agreements and committed fraudulent and negligent misrepresentations. The jury rendered a verdict on July 31, 2009, awarding the plaintiffs a total of $2.6 million in actual damages and $4.0 million in punitive damages. While the court struck the award of punitive damages on March 31, 2010, it denied the Company s

Table of Contents

motion to set aside the verdict or order a new trial. The Company timely filed a notice of appeal with the U.S. Court of Appeals for the Seventh Circuit in respect of the remaining actual damages. On August 24, 2011, the U.S. Court of Appeals for the Seventh Circuit issued its decision affirming the order of the lower court setting aside the award of punitive damages. In addition, the appellate court affirmed the lower court s finding of liability against the Company, but vacated the lower court s damages award of $2.6 million in compensatory damages as being not supported by the record and being too speculative. The case was then remanded to the lower court for a recalculation of damages that is consistent with the appellate court s decision. On May 17, 2012, the lower court ordered a new trial on the issue of damages. It is anticipated that the new trial will be conducted during the first half of 2013.

The Company has considered the facts of the case, the related case law and the decision of the U.S. Court of Appeals for the Seventh Circuit and, based on this information, believes that the verdict rendered on July 31, 2009 was inappropriate given the related facts and supporting legal arguments. The Company has considered the progress of the case, the views of legal counsel, the facts and arguments presented at the original jury trial, and the decision of the U.S. Court of Appeals for the Seventh Circuit and the fact that the Company intends to continue to vigorously defend its position through the remand proceedings in assessing the probability of a loss occurring for this matter. The Company has determined that a loss is reasonably possible. The Company estimates the high end of the range to be $2.6 million, the amount of the initial jury verdict, minus the punitive damage award. The Company believes it continues to have a strong defense against these claims and is vigorously contesting these allegations. After assessing all relevant information, the Company has accrued an amount at the low end of the range, which is deemed immaterial.

In addition to the item noted above, the Company is 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 the Company s consolidated financial statements.

15. Subsequent Events

On October 4, 2012, the Company acquired OrthoHelix. In the transaction, the Company paid consideration consisting of $100 million cash and 1,941,270 of the Company s ordinary shares (which was determined to be equal to $35 million divided by the average closing sale price per ordinary share during the five trading days immediately prior to and after the date of the Company s initial public announcement of the merger agreement). In addition, the Company agreed to make additional earn-out payments in cash of up to an aggregate of $20 million based upon the Company s sales of lower extremity joints and trauma products during fiscal years 2013 and 2014. A portion of the transaction consideration consisting of $11 million cash was deposited with an escrow agent to fund payment obligations with respect to a post-closing working capital adjustment and post-closing indemnification obligations of OrthoHelix s former equity holders. In addition, a portion of the earn-out payments are subject to certain rights of set-off for post-closing indemnification obligations of OrthoHelix s equity holders.

The Company has not disclosed the acquisition date fair value of the consideration transferred, the fair value of the assets and liabilities acquired, or the pro forma consolidated condensed income statement for the interim periods ended September 30, 2012 and October 2, 2011 as its valuation and purchase accounting for this transaction are not yet complete.

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

Table of Contents

ITEM 2. 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 unaudited consolidated financial statements and the notes thereto included elsewhere in this report, and other financial information included in this 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 Special Note Regarding Forward-Looking Statements and elsewhere in this 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 110 product lines in over 35 countries, including products acquired as a result of our acquisition of OrthoHelix subsequent to September 30, 2012.

We believe we are differentiated by our full portfolio of upper and lower extremity products, our extremity-focused sales organization and our strategic focus on extremities. We further believe that we are well positioned to benefit from the opportunities in the extremity products marketplace as we are among the global leaders in the shoulder and ankle joint replacement markets. We also have expanded our technology base and product offering to include: new joint replacement products based on new designs and materials; improved trauma products based on innovative designs; proprietary biologic materials for soft tissue repair; and the innovative lower extremity products of OrthoHelix, our recent acquisition. 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.

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

In the United States, we sell products from our upper extremity joints and trauma, lower extremity joints and trauma, and sports medicine and biologics product categories; we do not actively market large joints in the United States. While we market our products to extremity specialists, our revenue is generated from sales to healthcare institutions and distributors. We sell through a focused sales channel consisting of a network of mostly independent commission-based sales agencies, with some direct sales organizations in certain territories. Internationally, in select markets, we sell our full product portfolio, including upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics and large joints. We utilize several distribution approaches depending on the individual market requirements, including direct sales organizations in the largest European markets and Australia, and independent distributors for most other international markets. In the second quarter of 2012, we opened a direct sales office in Japan and received additional product registrations in China. For the nine months ended September 30, 2012, we generated revenue of $198.5 million, 56% of which was in the United States and 44% of which was international.

We have significantly grown our business during the past several years and 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 during such time. During the past several years, we also have increased our operating expenses significantly. We have strategically invested with particular emphasis on product development, acquisition of strategic products and technologies, manufacturing capacity, sales commissions and infrastructure to support both current and anticipated growth.

We have commenced a facilities consolidation initiative pursuant to which we intend to consolidate a number of our facilities in France, Ireland and the United States. The facilities consolidation initiative is driven by our strategy to drive operational productivity and to realize operating costs savings beginning in 2013. Under the initiative, we consolidated our Dunmanway, Ireland manufacturing facility into our Macroom, Ireland manufacturing facility during the second quarter of 2012. We also leased a new facility located in Bloomington, Minnesota to use as our U.S. business headquarters and for the consolidation of our Minneapolis-based marketing, training, regulatory, clinical, supply chain and corporate functions with our Stafford, Texas-based distribution operations, which are expected to be finalized during the fourth quarter of 2012. During the third quarter of 2012, we consolidated our St. Ismier, France manufacturing facility into our existing Montbonnot, France manufacturing facility. We anticipate that, in connection with implementing the facilities consolidation initiative, we will record pre-tax charges of approximately $6 to $7 million,

14

Table of Contents

comprised of one-time employee termination costs; facility closure, moving and related expenses; fixed asset write-offs net of anticipated proceeds from the sale of facilities in Stafford, Texas and Dunmanway, Ireland; and other miscellaneous related charges. We expect to record substantially all of the charges during 2012. During the nine months ended September 30, 2012, we recorded $5.3 million of expense related to the facilities consolidation initiative.

Recent Developments

On October 4, 2012, we acquired OrthoHelix Surgical Designs, Inc. In the transaction, we paid consideration consisting of $100 million cash and 1,941,270 of our ordinary shares (which was determined to be equal to $35 million divided by the average closing sale price per ordinary share during the five trading days immediately prior to and after the date of our initial public announcement of the merger agreement). In addition, we agreed to make additional earn-out payments in cash of up to an aggregate of $20 million based upon our sales of lower extremity joints and trauma products during fiscal years 2013 and 2014. A portion of the transaction consideration consisting of $11 million cash was deposited with an escrow agent to fund payment obligations with respect to a post-closing working capital adjustment and post-closing indemnification obligations of OrthoHelix s former equity holders. In addition, a portion of the earn-out payments are subject to certain rights of set-off for post-closing indemnification obligations of OrthoHelix s equity holders.

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

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 both the nine months ended September 30, 2012 and October 2, 2011, approximately 44% of our revenue was denominated in foreign currencies. As a result, our revenue can be significantly impacted by fluctuations in foreign currency exchange rates. We expect that foreign currencies will continue to represent a similarly significant percentage of our revenue 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. In addition, we also have significant levels of other selling, general and administrative expenses and research and development expenses denominated in foreign currencies. Historically, our non-U.S. Dollar revenue and expenses have been generally balanced, however, as our business continues to grow, fluctuations in these balances could affect operating results. At that time, we may pursue a derivative program to hedge this risk.

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 future periods in which that inventory is sold. Fluctuations in the value of foreign currencies relative to the U.S. dollar impact our operating results. Impacts associated with fluctuations in foreign currency exchange rates are discussed in more detail under Item 3 Quantitative and Qualitative Disclosures about Market Risk. In countries with functional currencies other than the U.S. dollar, assets and liabilities are translated into U.S. dollars using end-of-period exchange rates; and revenues, expenses and cash flows are translated using average rates of exchange. Constant currency growth rates used in the following discussion of results of operations eliminate the impact of period-over-period foreign currency fluctuations.

15

Table of Contents

We evaluate our results of operations on both an as reported and a constant currency basis. The constant currency presentation is a non-GAAP financial measure, which excludes the impact of fluctuations in foreign currency exchange rates. We believe providing constant currency information provides valuable supplemental information regarding our results of operations, consistent with how we evaluate our performance. We calculate constant currency percentages by converting our current-period local currency financial results using the prior-period foreign currency exchange rates and comparing these adjusted amounts to our prior-period reported results. This calculation may differ from similarly-titled measures used by others; and, accordingly, the constant currency presentation is not meant to be a substitution for recorded amounts presented in conformity with GAAP nor should such amounts be considered in isolation.

Table of Contents

Results of Operations

The three and nine months ended September 30, 2012 and October 2, 2011 each consisted of 13 and 39 weeks, respectively. The following table sets forth, for the periods indicated, our results of operations as a percentage of revenue:

	Three months ended				Nine months ended			
	September 30, 2012		October 2, 2011		September 30, 2012		October 2, 2011	
	(in thousands)				(in thousands)			
Statements of Operations Data:								
Revenue	$ 58,015	100%	$ 57,556	100%	$ 198,487	100%	$ 192,149	100%
Cost of goods sold	15,730	27%	16,650	29%	54,944	28%	54,708	28%
Gross profit	42,285	73%	40,906	71%	143,543	72%	137,441	72%
Selling, general and administrative	38,524	66%	37,937	66%	124,157	62%	119,895	62%
Research and development	5,260	9%	4,309	7%	16,329	8%	14,608	8%
Amortization of intangible assets	2,730	5%	2,741	5%	8,013	4%	8,448	4%
Special charges	6,503	11%	56	0%	9,413	5%	188	0%
Operating loss	(10,732)	(18)%	(4,137)	(7)%	(14,369)	(7)%	(5,698)	(3)%
Interest income	70	0%	145	0%	304	0%	415	0%
Interest expense	(481)	(1)%	(524)	(1)%	(1,430)	(1)%	(3,761)	(2)%
Foreign currency transaction loss	(326)	(1)%	(228)	(0)%	(195)	(0)%	(81)	(0)%
Loss on extinguishment of debt		*		*		*	(29,475)	(15)%
Other non-operating income (expense)	56	0%	993	2%	54	0%	1,009	1%
Loss before income taxes	(11,413)	(19)%	(3,751)	(7)%	(15,636)	(8)%	(37,591)	(20)%
Income tax (expense) benefit	(268)	(0)%	2,114	4%	(1,305)	(1)%	9,116	5%
Consolidated net loss	$ (11,681)	(20)%	(1,637)	(3)%	(16,941)	(8)%	(28,475)	(15)%

* Not meaningful

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:

	Three months ended				Nine months ended			
Revenue by Product Category	September 30, 2012	October 2, 2011	Percent change (as reported)	Percent change (constant currency)	September 30, 2012	October 2, 2011	Percent change (as reported)	Percent change (constant currency)
	($ in thousands)				($ in thousands)			
Upper extremity joints and trauma	$ 39,429	$ 37,690	5%	8%	$ 129,434	$ 120,640	7%	10%
Lower extremity joints and trauma	5,815	5,943	(2)	0	19,333	19,023	2	3
Sports medicine and biologics	3,487	3,329	5	8	11,363	10,769	6	8
Total extremities	48,731	46,962	4	7	160,130	150,432	6	9
Large joints and other	9,284	10,594	(12)	(1)	38,357	41,717	(8)	0
Total	$ 58,015	$ 57,556	1%	5%	$ 198,487	$ 192,149	3%	7%

Revenue by Geography	Three months ended September 30, 2012 ($ in thousands)	October 2, 2011	Percent change (as reported)	Percent change (constant currency)	Nine months ended September 30, 2012 ($ in thousands)	October 2, 2011	Percent change (as reported)	Percent change (constant currency)
United States	$ 34,377	$ 32,781	5%	5%	$ 110,647	$ 104,197	6%	6%
International	23,638	24,775	(5)	6	87,840	87,952	(0)	8
Total	$ 58,015	$ 57,556	1%	5%	$ 198,487	$ 192,149	3%	7%

Table of Contents

Comparison of three months ended September 30, 2012 to three months ended October 2, 2011

Revenue. Revenue increased by 1% to $58.0 million for the third quarter of 2012 from $57.6 million for the third quarter of 2011, as a result of increased sales in our upper extremity joints and trauma category, partially offset by a decrease in sales of large joints and other. Our revenue was negatively impacted by foreign currency exchange rate fluctuations of approximately $2.7 million, principally due to the performance of the U.S. dollar against the Euro. Excluding the impact of foreign currency exchange rate fluctuations, revenue increased by 5% for the third quarter of 2012 from the third quarter of 2011. The most significant increase occurred in our upper extremity joints and trauma category. The growth experienced was due primarily to increased demand and product expansion, partially offset by pricing pressures experienced in certain geographics. Our overall revenue growth of $0.5 million consisted of 5% growth in the United States, partially offset by a revenue decrease of 5% in our international geographies.

Revenue by product category. Revenue in upper extremity joints and trauma increased by 5% to $39.4 million for the third quarter of 2012 from $37.7 million for the third quarter of 2011, primarily as a result of the continued increase in sales of our Aequalis reversed and Aequalis Ascend shoulder products, and to a lesser degree, our Simpliciti shoulder products. We believe that increased sales of our Aequalis reversed shoulder products resulted from continued market growth in shoulder replacement procedures and continued market movement towards reversed shoulder replacement procedures. We also saw an increase in sales of our Aequalis Ascend shoulder products which continued to gain share in the shoulder replacement market. Offsetting this increase was the negative impact of foreign currency exchange rate fluctuations of $1.2 million. Revenue in our lower extremity joints and trauma decreased by 2% to $5.8 million for the third quarter of 2012 from $5.9 million for the third quarter of 2011, primarily due to fluctuations in exchange rates and a decrease in total ankle procedures in certain parts of Europe, partially offset by growth in such procedures in the U.S. Revenue in sports medicine and biologics increased by 5% to $3.5 million for the third quarter of 2012 from $3.3 million for the third quarter of 2011. This increase was attributable to increased sales of our anchor products internationally, partially offset by a decrease in sales of our biologics products. Revenue from large joints and other decreased by 12% to $9.3 million for the third quarter of 2012 from $10.6 million for the third quarter of 2011 related primarily to negative foreign currency exchange rate fluctuations of $1.2 million. Excluding the impact of foreign currency fluctuations, our large joints and other product category decreased by 1% in the third quarter of 2012 compared to the third quarter of 2011 primarily as a result of a decrease in the sales of our knee products due to continued economic pressures in our southern European geographies.

Revenue by geography. Revenue in the United States increased by 5% to $34.4 million for the third quarter of 2012 from $32.8 million for the third quarter of 2011, primarily driven by the continued increase in sales of upper extremities joints and trauma products, partially offset by the negative impact on sales as a result of certain distribution channel changes made during 2012. International revenue decreased by 5% to $23.6 million for the third quarter of 2012 from $24.8 million for the third quarter of 2011 related primarily to negative foreign currency exchange rate fluctuations of $2.7 million. Excluding the impact of foreign currency exchange rate fluctuations, our international revenue increased by 6%. This increase was primarily due to increased revenue in Australia and the establishment of a direct sales office in Belgium, which also serves Luxembourg, through the acquisition of our previous exclusive distributor in these territories, partially offset by a negative impact on sales in certain Western European countries due to austerity measures and lower procedure volumes.

Cost of goods sold. Our cost of goods sold decreased to $15.7 million for the third quarter of 2012 from $16.7 million for the third quarter of 2011. As a percentage of revenue, cost of goods sold decreased from 29% for the third quarter of 2011 to 27% for the third quarter of 2012, primarily due to a lower level of excess and obsolete inventory charges in the third quarter of 2012 and lower internal manufacturing costs. Our cost of goods sold and corresponding gross profit as a percentage of revenue can be expected to fluctuate in future periods depending upon certain factors, including, among others, changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, plans for insourcing some previously outsourced production activities, inventory reserves required, levels of production volume and fluctuating inventory costs due to changes in foreign currency exchange rates since the period they were manufactured.

Selling, general and administrative. Our selling, general and administrative expenses increased by 2% to $38.5 million for the third quarter of 2012 from $37.9 million for the third quarter of 2011. As a percentage of revenue, selling, general and administrative expenses were 66% for both the three months ended September 30, 2012 and the three months ended October 2, 2011. Our variable selling costs as a percentage of revenue were slightly higher during the third quarter of 2012 when compared to the third quarter of 2011. The increase in total selling, general and administrative expense was primarily a result of additional variable sales expenses and non-variable sales expenses including strategic investments in our US sales organization, training and education, expansion into Japan and conversion to a direct distribution channel in Belgium. Partially offsetting this increase is a decrease in share based compensation, legal fees and expenses related to certain management incentives. Also affecting selling, general and administrative expenses was the favorable impact of foreign currency exchange rate fluctuations of $2.4 million.

Table of Contents

Research and development. Research and development expenses increased by 22% to $5.3 million for the third quarter of 2012 from $4.3 million for the third quarter of 2011. As a percentage of revenue, research and development expenses grew 2% to 9% for the three months ended September 30, 2012 from 7% for the three months ended October 2, 2011. The increase in total research and development expense was primarily due to increased clinical study related expenses, an increased level of expenses on certain shoulder and biologic related product development projects and increased personnel related expenses. These items were partially offset by the favorable impact of foreign currency exchange rate fluctuations of $0.3 million. 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 in the near future, research and development expenses as a percentage of revenue will remain consistent with past levels.

Amortization of intangible assets. Amortization of intangible assets remained flat at $2.7 million for both the third quarter of 2012 and the third quarter of 2011.

Special charges. Special charges were $6.5 million for the three months ended September 30, 2012 compared to $0.1 million for the three months ended October 2, 2011. Special charges included approximately $2.8 million of expense for the three months ended September 30, 2012 related to our facilities consolidation initiative. The $2.8 million is comprised of employee-benefit related expenses including severance and retention of terminated employees in the U.S., moving and transportation expenses, impairment charges on fixed assets related to the impacted facilities of Stafford, Texas and Dunmanway, Ireland, lease termination costs related to the Edina, Minnesota facility, professional fees and other expenses. Also included in special charges for the three months ended September 30, 2012 is approximately $2.0 million of bad debt expense related to the termination of a distributor and worsening general economic conditions in Italy, $0.8 million of expense related to certain distribution changes in the U.S. and internationally, including the closure of our Spanish sales office, and $1.0 million of acquisition integration costs related to the acquisition of OrthoHelix. Refer to Note 13 for further details on the facility consolidation initiative and other special charges.

Interest income. Our interest income remained consistent at $0.1 million during the third quarter of 2012 and the third quarter of 2011.

Interest expense. Our interest expense was $0.5 million for both the third quarter of 2012 and the third quarter of 2011. Our interest expense for the third quarters of 2012 and 2011 related to the interest paid on our prior term loans, mortgages and prior lines of credit and overdraft arrangements.

Foreign currency transaction loss. We recognized $0.3 million of foreign currency transaction loss in the third quarter of 2012 compared to a foreign currency transaction loss of $0.2 million for the third quarter of 2011. Foreign currency gains and losses are recognized when a transaction is denominated in a currency other than the subsidiary s functional currency. The increase in foreign currency transaction loss was primarily attributable to foreign currency exchange rate fluctuations on foreign currency denominated intercompany payables and receivables.

Other non-operating income. Our other non-operating income decreased to $0.1 million for the three months ended September 30, 2012 from $1.0 million for the three months ended October 2, 2011. The $1.0 million related to the third quarter of 2011 was primarily due to the recognition of a gain related to the resolution of a contingent liability recorded as part of the acquisition of C2M Medical, Inc. The contingent liability related to remaining earn-out payments on sales of our Piton anchor products. The earn-out period ended during the third quarter of 2011 and the remaining liability was reversed and a gain was recognized in the same quarter.

Income tax (expense) benefit. Our effective tax rate for the third quarter of 2012 and 2011 was 2% and 56%, respectively. The change in our effective tax rate from the third quarter of 2011 to the third quarter of 2012 primarily relates to the relative percentage of our pre-tax income from operations in countries with related income tax expense compared to operations in countries in which we have pre-tax losses but for which we record a valuation allowance against our deferred tax assets, and thus, cannot recognize income tax benefits. We recorded a minimal income tax expense during the third quarter of 2012 compared to a benefit of $2.1 million for the third quarter of 2011. 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 geographies.

Comparison of nine months ended September 30, 2012 to nine months ended October 2, 2011

Revenue. Revenue increased by 3% to $198.5 million for the nine months ended September 30, 2012 from $192.1 million for the nine months ended October 2, 2011, as a result of increased sales in each of our extremity categories, partially offset by a decrease in sales of large joints and other. The most significant increase occurred in our upper extremity joints and trauma category. The growth experienced in the extremity categories was due primarily to increased demand and product expansion, partially offset by pricing pressures experienced in certain geographies. Our overall revenue growth of $6.3 million consisted of 6% growth in the United States while growth in our international geographies remained consistent with the same period of the prior year. Our revenue was negatively impacted by foreign currency exchange rate fluctuations of approximately $7.1 million, principally due to the performance of the U.S. dollar against the Euro. Excluding the impact of

foreign currency exchange rate fluctuations, revenue grew by 7%.

Table of Contents

Revenue by product category. Revenue in upper extremity joints and trauma increased by 7% to $129.4 million for the nine months ended September 30, 2012 from $120.6 million for the nine months ended October 2, 2011, primarily as a result of the continued increase in sales of our Aequalis reversed and Aequalis Ascend shoulder products, and to a lesser degree, our Simpliciti shoulder products. We believe that increased sales of our Aequalis reversed shoulder products resulted from continued market growth in shoulder replacement procedures and continued market movement towards reversed shoulder replacement procedures. We also saw an increase in sales of our Aequalis Ascend shoulder products which continued to gain share in the shoulder replacement market. Offsetting this increase was the negative impact of foreign currency exchange rate fluctuations of $3.0 million. Revenue in our lower extremity joints and trauma increased by 2% to $19.3 million for the nine months ended September 30, 2012 from $19.0 million for the nine months ended October 2, 2011, primarily due to increased sales in our ankle replacement and ankle fusion products in the United States. Revenue in sports medicine and biologics increased by 6% to $11.4 million for the nine months ended September 30, 2012 from $10.8 million for the nine months ended October 2, 2011. This increase was primarily attributable to increased sales of our anchor products internationally, partially offset by a decrease in sales of our biologics products. Revenue from large joints and other decreased by 8% to $38.4 million for the nine months ended September 30, 2012 from $41.7 million for the nine months ended October 2, 2011 primarily related to negative foreign currency exchange rate fluctuations of $6.4 million. Excluding the impact of foreign currency exchange rate fluctuations, our large joints and other product category remained flat for the nine months ended September 30, 2012 compared to the nine months ended October 2, 2011.

Revenue by geography. Revenue in the United States increased by 6% to $110.6 million for the nine months ended September 30, 2012 from $104.2 million for the nine months ended October 2, 2011. While the United States revenue was negatively affected by certain distribution channel changes made during the nine months ended September 30, 2012, overall United States revenue increased as a result of increases in sales in upper extremity joints and trauma and lower extremity joints and trauma. International revenue decreased slightly to $87.8 million for the nine months ended September 30, 2012 from $88.0 million for the nine months ended October 2, 2011. This decrease in international sales was due to the negative impact of foreign currency exchange rate fluctuations of $7.1 million. Excluding the impact of foreign currency exchange rate fluctuations, our international revenue increased by 8%. This increase was primarily due to increased revenue in France, Australia, the United Kingdom and sales to certain stocking distributors across various countries in which we have no current direct sales force.

Cost of goods sold. Our cost of goods sold increased slightly to $54.9 million for the nine months ended September 30, 2012 from $54.7 million for the nine months ended October 2, 2011. As a percentage of revenue, cost of goods sold remained consistent at 28% for the nine months ended September 30, 2012 and October 2, 2011. Our cost of goods sold and corresponding gross profit as a percentage of revenue can be expected to fluctuate in future periods depending upon certain factors, including, among others, changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, plans for insourcing some previously outsourced production activities, inventory reserves required, levels of production volume and fluctuating inventory costs due to changes in foreign currency exchange rates since the period they were manufactured.

Selling, general and administrative. Our selling, general and administrative expenses increased by 4% to $124.2 million for the nine months ended September 30, 2012 from $119.9 million for the nine months ended October 2, 2011. As a percentage of revenue, selling, general and administrative expenses grew 1% to 63% for the nine months ended September 30, 2012 from 62% for the nine months ended October 2, 2011. Our variable selling costs as a percentage of revenue were slightly higher during the first nine months of 2012 when compared to the same period of 2011, which was offset by a lower rate of non-variable selling related expenses as a percentage of revenue. The increase in total selling, general and administrative expense was primarily a result of $1.9 million of additional variable expenses including commissions, royalties and freight expenses due to increased revenue. Selling, general and administrative expenses also increased compared to the nine months ended October 2, 2011 as a result of increased instrument depreciation, sales management costs and costs related to information technology, partially offset by a decrease in expenses related to certain management incentives. These items were partially offset by the favorable impact of foreign currency exchange rate fluctuations of $5.2 million.

Research and development. Research and development expenses increased by 12% to $16.3 million for the nine months ended September 30, 2012 from $14.6 million for the nine months ended October 2, 2011. As a percentage of revenue, research and development expenses remained consistent with the prior year period at 8%. The increase in total research and development expense of $1.7 million was primarily due to increased clinical study related expenses, an increased level of expenses on certain shoulder related development projects including the Ascend Flex, other biologics related development projects and increased personnel related expenses. These items were partially offset by the favorable impact of foreign currency exchange rate fluctuations of $0.7 million and a decrease in expenses related to certain management incentives. 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 in the near future, research and development expenses as a percentage of revenue will remain consistent with past levels.

Table of Contents

Amortization of intangible assets. Amortization of intangible assets decreased by 5% to $8.0 million for the nine months ended September 30, 2012 from $8.4 million for the nine months ended October 2, 2011, primarily as a result of the complete amortization of certain license related intangibles, partially offset by intangible assets recorded through the acquisition of our stocking distributor in Belgium and Luxembourg in the second quarter of 2012.

Special charges. Special charges were $9.4 million for the nine months ended September 30, 2012 compared to $0.2 million for the nine months ended October 2, 2011. Special charges included approximately $5.3 million of expense for the nine months ended September 30, 2012 related to our facilities consolidation initiative. The $5.3 million is comprised of employee-benefit related expenses including severance and retention of terminated employees in the U.S., moving and transportation expenses, impairment charges on fixed assets related to the impacted facilities of Stafford, Texas and Dunmanway, Ireland, lease termination costs related to the Edina, Minnesota facility, professional fees and other expenses. Also included in special charges for the three months ended September 30, 2012 is approximately $2.0 million of bad debt expense related to the termination of a distributor and worsening general economic conditions in Italy, $0.8 million of expense related to certain distribution changes in the U.S. and internationally, including the closure of our Spanish sales office, $1.0 million of integration costs related to the acquisition OrthoHelix and our exclusive distributor in Belgium and Luxembourg and $0.4 million of expense related to departure of our former Global Chief Financial Officer. For the nine months ended October 2, 2011, the $0.2 million of special charges were primarily related to the closure of our Beverly, Massachusetts research and development facility. Refer to Note 13 for further details on the facility consolidation initiative and other special charges.

Interest income. Our interest income decreased by 27% to $0.3 million for the nine months ended September 30, 2012 from $0.4 million for the nine months ended October 2, 2011primarily as a result of decreased average interest rates.

Interest expense. Our interest expense decreased by 62% to $1.4 million for the nine months ended September 30, 2012 from $3.8 million for the nine months ended October 2, 2011 due to the repayment of our notes payable in February 2011. Our notes payable carried an 8% stated annual interest rate and were recorded at a discount because they were issued together with warrants. The discount on our notes payable was also previously amortized as additional interest expense. As a result, the existence of our notes payable in prior periods caused a much higher level of interest expense. Our interest expense for the nine months ended September 30, 2012 related primarily to the interest paid on our prior term loans, mortgages, and prior lines of credit and overdraft arrangements.

Foreign currency transaction gain. We recognized $0.2 million of foreign currency transaction gain in the nine months ended September 30, 2012 compared to $0.1 million for the nine months ended October 2, 2011. Foreign currency gains and losses are recognized when a transaction is denominated in a currency other than the subsidiary s functional currency and are primarily attributable to foreign currency exchange rate fluctuations on foreign currency denominated intercompany payables and receivables.

Loss on extinguishment of debt. We recognized a $29.5 million loss on extinguishment of debt during the nine months ended October 2, 2011 due to the repayment of our notes payable. Our notes payable were issued in 2008 and 2009 together with warrants to purchase ordinary shares of our company. At the time of issuance, we recognized the estimated fair value of the warrants as a warrant liability with an offsetting debt discount to reduce the carrying value of the notes payable to the estimated fair value at the time of issuance. This debt discount was then amortized as additional interest expense over the term of the notes. At the time of repayment in the first quarter of 2011, we recognized the remaining unamortized portion of the discount as a loss on the extinguishment of debt. We had no such expense related to the extinguishment of debt during the nine months ended September 30, 2012. See Note 9 of our consolidated financial statements for further discussion of the accounting treatment of the notes payable and related warrants.

Other non-operating income. Our other non-operating income decreased to $0.1 million during the nine months ended September 30, 2012 from $1.0 million during the nine months ended October 2, 2011. The $1.0 million related to the third quarter of 2011 was primarily due to the recognition of a gain related to the resolution of our contingent liability recorded as a part of the acquisition of C2M Medical Inc. The contingent liability related to remaining earn-out payments on sales of our Piton anchor products. The earn-out period ended during the third quarter of 2011 and the remaining liability was reversed and, as a result, was recognized as a gain in the same quarter.

Income tax (expense) benefit. Our effective tax rate for the nine months ended September 30, 2012 and nine months ended October 2, 2011 was 8% and 24%, respectively. The change in our effective tax rate from the nine months ended October 2, 2011 to the nine months ended September 30, 2012 primarily relates to the relative percentage of our pre-tax income from operations in countries with related income tax expense compared to operations in countries in which we have pre-tax losses but for which we record a valuation allowance against deferred tax assets, and thus, cannot recognize income tax benefits. During the nine months ended September 30, 2012, our income tax expense recognized related primarily to income tax on pre-tax income in certain of our European operations. This pre-tax income was partially offset by pre-tax losses in our United States and Netherlands operations for which we currently do not recognize any income tax benefits. Our income tax expense increased to $1.3 million during the nine

21

Table of Contents

months ended September 30, 2012 compared to an income tax benefit of $9.1 million for the nine months ended October 2, 2011. During the nine months ended October 2, 2011, we recognized $7.5 million of deferred tax benefit related to the $29.5 million loss on extinguishment of debt previously discussed. This benefit was the result of reversing the remaining deferred tax liability related to the unamortized debt discount on our notes payable at the time of repayment. 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 geographies.

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

Liquidity and Capital Resources

Since inception, we have generated significant operating losses. These, combined with significant charges not related to cash from operations, which have included amortization of acquired intangible assets, fair value adjustments to our warrant liability and accretion of noncontrolling interests, have resulted in an accumulated deficit of $230.9 million as of September 30, 2012. 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 then current shareholders and new investors and other bank related debt. In February 2011, we completed an initial public offering from which we received net proceeds of approximately $149.2 million after underwriters discounts, commissions and offering expenses. Additionally, in March 2011, we sold additional ordinary shares due to the exercise of the underwriters overallotment option from which we received additional net proceeds of approximately $12.8 million after underwriters discounts and commissions and offering expenses. Our notes payable were repaid in full during the first quarter of 2011 using a portion of these combined proceeds.

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

	As of	
	September 30, 2012	January 1, 2012
	($ in thousands)	
Cash and cash equivalents	$ 58,499	$ 54,706
Working capital	129,390	133,398

On October 4, 2012, we acquired OrthoHelix Surgical Designs, Inc. In the transaction, we paid consideration consisting of $100 million cash and 1,941,270 of our ordinary shares (which was determined to be equal to $35 million divided by the average closing sale price per ordinary share during the five trading days immediately prior to and after the date of our initial public announcement of the merger agreement). In addition, we agreed to make additional earn-out payments in cash of up to an aggregate of $20 million based upon our sales of lower extremity joints and trauma products during fiscal years 2013 and 2014. A portion of the transaction consideration consisting of $11 million cash was deposited with an escrow agent to fund payment obligations with respect to a post-closing working capital adjustment and post-closing indemnification obligations of OrthoHelix s former equity holders. In addition, a portion of the earn-out payments are subject to certain rights of set-off for post-closing indemnification obligations of OrthoHelix s equity holders.

In connection with our acquisition of OrthoHelix, which closed on October 4, 2012, we entered into a new credit agreement. Under the credit agreement, we borrowed $145 million, consisting of: (1) a senior secured term loan facility to Tornier USA denominated in dollars in an aggregate principal amount of up to U.S. $75 million (referred to as the USD term loan facility); (2) a senior secured term loan facility to Tornier USA denominated in euros in an aggregate principal amount of up to the U.S. dollar equivalent of U.S. $40 million (referred to as the EUR term loan facility); and (3) a senior secured revolving credit facility to Tornier USA denominated at the election of Tornier USA, in U.S. dollars, euros, pounds, sterling and yen in an aggregate principal amount of up to the U.S. dollar equivalent of U.S. $30 million. Funds available under the new revolving credit facility may be used for general corporate purposes.

22

Table of Contents

The borrowings under the term loan facilities were used at the closing of our acquisition of OrthoHelix to pay the consideration for such acquisition, and such fees, costs and expenses incurred in connection with the acquisition and the credit agreement and to repay prior existing indebtedness of us and our subsidiaries. The credit agreement contains customary covenants, including financial covenants which require us to maintain minimum interest coverage and maximum total net leverage ratios, and customary events of default. The obligations under the credit agreement are guaranteed by us, Tornier USA and certain other of our subsidiaries, and subject to certain exceptions, are secured by a first priority security interest in substantially all of our assets and the assets of certain of our existing and future subsidiaries of Tornier.

At the option of Tornier USA, loans under our new revolving credit facility and USD term facility bear interest at (a) the alternate base rate (if denominated in U.S. dollars), equal to the greatest of (i) the prime rate in effect on such day, (ii) the federal funds effective rate in effect on such day plus 1/2 of 1%, and (iii) the adjusted LIBO rate (as defined in our new credit agreement) plus 1%) plus in the case of each of (i)-(iii) above, an applicable rate of 2.00% or 2.25% (depending on our total net leverage ratio (as defined in our new credit agreement)), or (b) in the case of a eurocurrency loan (as defined in our new credit agreement), at the applicable adjusted LIBO rate for the relevant interest period plus an applicable rate of 3.00% or 3.25% (depending on our total net leverage ratio), plus the mandatory cost (as defined in our new credit agreement) if such loan is made in a currency other than dollars of any lender our new credit agreement (other than a lender to our new credit agreement on October 4, 2012) from a lending office in the United Kingdom or a participating member state (as defined in our new credit agreement). Under the EUR term facility, (a) alternate base rate loans bear interest at the alternate base rate plus the applicable rate, which is 3.00% or 3.25% (depending on our total net leverage ratio) and (b) eurocurrency loans bear interest at the adjusted LIBO rate for the relevant interest period, plus an applicable rate, which is 4.00% or 4.25% (depending on our total net leverage ratio), plus the mandatory cost, if applicable.

We believe that our cash and cash equivalents balance of approximately $58.5 million as of September 30, 2012, of which $29.4 million was used in the acquisition of OrthoHelix subsequent to September 30, 2012, along with available credit under our new revolving credit facility will be sufficient to fund our working capital requirements and operations and permit anticipated capital expenditures during the remainder of 2012. In the event that we would require additional working capital to fund future operations or for other needs, we could seek to acquire that through additional issuances of equity or debt financing arrangements which may or may not be available on favorable terms at such time.

Operating activities. Net cash provided by operating activities was $11.1 million for the nine months ended September 30, 2012 compared to $11.0 million for the nine months ended October 2, 2011. While our net cash provided by operating activities was similar between these two periods, our net loss for the period last year of $28.5 million included a $22.0 million non-cash charge, net of tax, related to the extinguishment of debt. Excluding the impact of this charge, our net loss for the period last year was lower than the same period in 2012, but this was offset by higher cash used for working capital for the nine months ended October 2, 2011 compared to the nine months ended September 30, 2012.

Investing activities. Net cash used in investing activities totaled $20.8 million during the nine months ended September 30, 2012 compared to $20.9 million during the nine months ended October 2, 2011. The decrease in net cash used in investing activities is due to a reduction in the amount of instrument additions, partially offset by the acquisition of our sole and exclusive distributor in Belgium and Luxembourg and increased fixed asset purchases in the second quarter of 2012. Expenditures related to property, plant and equipment were $7.9 million and $3.8 million for the nine months ended September 30, 2012 and the nine months ended October 2, 2011, respectively. Fixed asset expenditures during the nine months ended September 30, 2012 were driven by our facility consolidation initiative. Acquisition related payments for the nine months ended September 30, 2012 included payments made in accordance with existing licensing agreements, in addition to the acquisition of our distributor mentioned above. Acquisition related payments for the nine months ended October 2, 2011 included the final acquisition related payment made in accordance with the contingent purchase price of the acquisition of our Piton technology.

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 decreased to $13.4 million during the nine months ended September 30, 2012, from $42.5 million during the nine months ended October 2, 2011. The nine months ended September 30, 2012 included approximately $5.2 million in proceeds from the issuance of long-term debt along with $9.4 million in draws on short-term debt in both France and the U.S. Additionally, approximately $6.9 million of cash was generated during the nine months ended September 30, 2012 as a result of the exercise of employee stock options. The net cash provided by financing activities in the nine months ended October 2, 2011 included the receipt of approximately $168.3 million from the completion of our initial public offering and subsequent exercise of the underwriters overallotment option, after underwriters discounts and commissions and offering expenses, partially offset by the repayment of our notes payable of $116.1 million.

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, 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.

Contractual Obligations and Commitments

We refer you to the description of our contractual obligations and commitments as of January 1, 2012 as set forth in our annual report on Form 10-K for the fiscal year ended January 1, 2012. There were no material changes to such information since that date through September 30, 2012, except for our new 126-month lease commitment related to our new Bloomington, Minnesota facility which includes total rent payments over the life of the lease of $6.2 million and commenced on July 1, 2012, and future earn-out obligations, aggregating up to approximately $1.0 million incurred in connection with the acquisition of our sole and exclusive distributor in Belgium and Luxembourg based on annual revenues of the acquired entity for the next two years.

Critical Accounting Policies

Information on judgments related to our most critical accounting policies and estimates is discussed in Item 7 of our annual report on Form 10-K for the year ended January 1, 2012. Certain of our more critical accounting estimates require the application of significant judgment by management in selecting the appropriate assumptions in determining the estimate. By their nature, these judgments are subject to an inherent degree of uncertainty. We develop these judgments based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. Actual results may differ from these judgments under different assumptions or conditions. Different, reasonable estimates could have been used for the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations. All of our significant accounting policies are more fully described in Note 2 to our consolidated financial statements set forth in our annual report on Form 10-K for the year ended January 1, 2012. There have been no significant changes to the policies related to our critical accounting estimates since January 1, 2012.

Table of Contents

ITEM 3. 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 prior various revolving lines of credit in the United States and in Europe generally bore interest at variable annual rates. Borrowings under our various term loans in the United States and Europe were mixed between variable and fixed interest rates. As of September 30, 2012, we had $18.1 million in borrowings under our revolving lines of credit and $28.9 million in borrowings under various term loans. Based upon this debt level, a 10% increase in the annual interest rate on such borrowings would not have a material impact on our interest expense.

At the option of Tornier USA, loans under our new revolving credit facility, which was established on October 4, 2012, and USD term facility bear interest at (a) the alternate base rate (if denominated in U.S. dollars), equal to the greatest of (i) the prime rate in effect on such day, (ii) the federal funds effective rate in effect on such day plus 1/2 of 1%, and (iii) the adjusted LIBO rate (as defined in our new credit agreement) plus 1%) plus in the case of each of (i)-(iii) above, an applicable rate of 2.00% or 2.25% (depending on our total net leverage ratio (as defined in our new credit agreement)), or (b) in the case of a eurocurrency loan (as defined in our new credit agreement), at the applicable adjusted LIBO rate for the relevant interest period plus an applicable rate of 3.00% or 3.25% (depending on our total net leverage ratio), plus the mandatory cost (as defined in our new credit agreement) if such loan is made in a currency other than dollars of any lender our new credit agreement (other than a lender to our new credit agreement on October 4, 2012) from a lending office in the United Kingdom or a participating member state (as defined in our new credit agreement). Under the EUR term facility, (a) alternate base rate loans bear interest at the alternate base rate plus the applicable rate, which is 3.00% or 3.25% (depending on our total net leverage ratio) and (b) eurocurrency loans bear interest at the adjusted LIBO rate for the relevant interest period, plus an applicable rate, which is 4.00% or 4.25% (depending on our total net leverage ratio), plus the mandatory cost, if applicable.

At September 30, 2012 our cash and cash equivalents were $58.5 million, of which $29.9 million was subsequently used to help fund the acquisition of OrthoHelix on October 4, 2012. Based on our annualized average interest rate, a 10% decrease in the annual interest rate on such balances would not result in a material impact on our interest income on an annual basis.

Foreign Currency Exchange Rate Risk

Fluctuations in the exchange rate between the U.S. dollar and foreign currencies could adversely affect our financial results. In both the nine months ended September 30, 2012 and October 2, 2011, approximately 44% of our revenues were denominated in foreign currencies. We expect that foreign currencies will continue to represent a similarly significant percentage of our revenues in the future. Operating expenses related to these revenues are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. However, for revenues 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. Historically, our non-U.S. Dollar revenue and expenses have been generally balanced, however, as our business continues to grow, fluctuations in these balances could affect operating results. At that time, we may pursue a derivative program to hedge this risk.

In the nine months ended September 30, 2012, approximately 79% of our revenues denominated in foreign currencies 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. 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 income/expense levels in the respective period and are reported in foreign currency transaction gain (loss) in our consolidated financial statements. In the third quarter of 2012, we began to economically hedge our balance sheet exposure to fluctuations in the Euro by entering into foreign exchange forward contracts. In future periods, we may hedge other foreign currency exposures.

25

Table of Contents

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our President and 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 our 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 September 30, 2012. Based on that review and evaluation, which included inquiries made to certain of our other employees, the Certifying Officers have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures, as designed and implemented, are effective in ensuring that information relating to our Company required to be disclosed in the reports that we file or submit 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 our management, including the Certifying Officers, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the third quarter of 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

A description of our legal proceedings in Note 14 of our consolidated financial statements included in this report is incorporated herein by reference.

ITEM 1A. RISK FACTORS.

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. The following is a discussion of the specific risks that could materially adversely affect our business, financial condition or operation results:

Risks Related to Our Business and Our Industry

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

We have a history of operating losses and at September 30, 2012, we had an accumulated deficit of $230.9 million. Our ability to achieve profitability will be influenced by many factors, including the extent and duration of our future operating losses, the level and timing of future revenue and expenditures, market acceptance of new products, the results and scope of ongoing research and development projects, competing technologies and market and regulatory developments. As a result, we may continue to incur operating losses for the foreseeable future. These losses will continue to have an adverse impact on shareholders equity, and we may never achieve or sustain profitability.

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

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

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

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

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

In the United States, we sell our products primarily through a sales channel consisting of mostly independent commission-based sales agencies, which utilize several sales representatives, with some direct sales organizations in certain territories. Internationally, we utilize several distribution approaches depending on the individual market requirements, including direct sales organizations in the largest European markets and Australia, and independent distributors for most other international markets. Our distributors and sales agencies do not sell our products exclusively and may offer similar products from other orthopaedic companies. In 2011 and during the nine months ended September 30, 2012, no individual distributor or sales agency accounted for more than 7% of our global revenue. Our success depends largely upon our ability to motivate our distributors and sales agencies to sell our products. Additionally, we depend on their sales and service expertise and relationships

with the surgeons in the marketplace. Our

Table of Contents

distributors and independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products or may focus their sales efforts on other products that produce greater commissions for them. If our relationship with any of our distributors or sales agencies terminated, we could enter into agreements with existing distributors and sales agencies to take on the related sales, contract with distributors and new sales agencies, or hire direct sales representatives or a combination of these options. A failure to maintain our existing relationships with our distributors and independent sales agencies and their representatives could have an adverse effect on our operations. We do not control our distributors or independent sales agencies and they may not be successful in implementing our marketing plans.

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

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

We have commenced a facilities consolidation initiative pursuant to which we intend to consolidate a number of our facilities in France, Ireland and the United States. The facilities consolidation initiative is driven by our strategy to drive operational productivity and to realize operating costs savings beginning in 2013. Under the initiative, we consolidated our Dunmanway, Ireland manufacturing facility into our Macroom, Ireland manufacturing facility during the second quarter of 2012. We also leased a new facility located in Bloomington, Minnesota to use as our U.S. business headquarters and for the consolidation of our Minneapolis-based marketing, training, regulatory, clinical, supply chain and corporate functions with our Stafford, Texas-based distribution operations, which are expected to be finalized during the fourth quarter of 2012. During the third quarter of 2012, we consolidated our St. Ismier, France manufacturing facility into our existing Montbonnot, France manufacturing facility. We anticipate that, in connection with implementing the facilities consolidation initiative, we will record pre-tax charges, comprised of one-time employee termination costs; facility closure, moving and related expenses; fixed asset write-offs net of anticipated proceeds from the sale of facilities in Stafford, Texas and Dunmanway, Ireland; and other miscellaneous related charges. We expect to record substantially all of the charges during 2012. During the nine months ended September 30, 2012, we recorded $5.3 million of expense related to the facilities consolidation initiative.

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

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

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

28

Table of Contents

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

We also compete against smaller, entrepreneurial companies with niche product lines. Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearances or approvals for competing products more rapidly than us and develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive. We also compete with other organizations in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies and technology licenses complementary to our products or advantageous to our business. If our competitors are more successful than us in these matters, we may be unable to compete successfully against our existing or future competitors.

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

We derive a significant portion of our revenue from operations in international markets. Our international distribution system consists of 10 direct sales offices and approximately 30 distribution partners, who sell in approximately 35 countries. Most of these countries are, to some degree, subject to political, economic and social instability. For the nine months ended September 30, 2012 and the year ended January 1, 2012, approximately 44% and 46% of our revenue was derived from our international operations. In 2012, we opened a direct sales office in Japan and we intend to further expand our international operations into key markets, such as Brazil and China. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations on orthopaedic implants and biologics products;
- the imposition of costly and lengthy new export license requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with that country, company, person or entity;
- economic instability, including the European sovereign debt crisis and the austerity measures taken and to be taken by certain countries in response to such crisis, and the currency risk between the U.S. dollar and foreign currencies in our target markets;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed upon us;

a shortage of high-quality international salespeople and distributors;

loss of any key personnel who possess proprietary knowledge or are otherwise important to our success in international markets;

changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may require us to sell our products at lower prices;

unexpected changes in foreign regulatory requirements;

differing local product preferences and product requirements;

changes in tariffs and other trade restrictions;

work stoppages or strikes in the healthcare industry;

difficulties in enforcing and defending intellectual property rights;

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

complex data privacy requirements and labor relations laws; and

exposure to different legal and political standards.

Table of Contents

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

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

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

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

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

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

30

Table of Contents

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

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

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

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

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

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

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

Our upper extremity joints and trauma products, which includes joint implants and bone fixation devices for the shoulder, hand, wrist and elbow, generate a significant portion of our revenue. During the nine months ended September 30, 2012 and the fiscal year ended January 1, 2012, our upper extremity joints and trauma products generated approximately 65% and 63%, respectively, of our revenue. We expect the shoulder to continue to be the largest and most important product category for us for the foreseeable future. A decline in revenue from these products as a result of increased competition, regulatory matters, intellectual property matters or any other reason would negatively impact our operating results.

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

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

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

Our private-label manufacturers are sole source suppliers of the products we purchase from them. Given the specialized nature of the products they provide, we may not be able to locate or establish additional or replacement manufacturers of these products. Moreover, these private-label manufacturers typically own the intellectual property associated with their products, and even if we could find a replacement manufacturer for the product, we may not have sufficient rights to enable the replacement party to manufacture the product. While we have entered into agreements with our private-label manufacturers to provide us sufficient quantities of products, we cannot assure you that they will do so, or that any products they do provide us will not contain defects in quality. Our private-label manufacturing agreements have terms expiring between

this year and 2015 and are renewable under certain conditions or by mutual agreement. The agreements also include some or all of the following provisions allowing for termination under certain circumstances: (i) either party s uncured material breach of the terms and conditions of the agreement, (ii) either party

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

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

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

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

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

Our U.S. operations, including those of our U.S. based subsidiary, Tornier, Inc., are currently subject to the U.S. Foreign Corrupt Practices Act, or the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of off books slush funds from which such improper payments can be made. We also are currently subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development s Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. We either operate or plan to operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, such as China and Brazil, and we utilize a number of third-party sales representatives for whose actions we could be held liable under the FCPA. We inform our personnel and third-party sales representatives of the requirements of the FCPA and other anticorruption laws, including, but not limited to their reporting requirements. We also have developed and will continue to develop and implement systems for formalizing contracting processes, performing due diligence on agents and improving our recordkeeping and auditing practices regarding these regulations. However, there is no guarantee that our employees, third-party sales representatives or other agents have not or will not engage in conduct undetected by our processes and for which we might be held responsible under the FCPA or other anticorruption laws.

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

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

32

Table of Contents

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

We use a number of suppliers for raw materials and select components that we need to manufacture our products. These suppliers must provide the materials and components to our standards for us to meet our quality and regulatory requirements. We obtain some key raw materials and select components from a single source or a limited number of sources. For example, we rely on one supplier for raw materials and select components in several of our products, including Poco Graphite, Inc., which supplies graphite for our pyrocarbon products, CeramTec AG, or CeramTec, which supplies ceramic for ceramic heads for hips, and Heymark Metals Ltd., which supplies Cobalt Chrome used in certain of our hip, shoulder and elbow products. Establishing additional or replacement suppliers for these components, and obtaining regulatory clearances or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business and operating results. We do not have contracts with our sole source suppliers (other than a Quality Assurance Agreement and Secrecy Agreement with CeramTec, which only relate to quality and confidentiality obligations of the parties and do not govern the purchase and receipt of CeramTec products) and instead rely on purchase orders. As a result, those suppliers may elect not to supply us with product or to supply us with less product than we need, and we will have limited rights to cause them to do otherwise. In addition, some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third parties could adversely and materially affect our reputation or commercialization of our products and adversely and materially affect our business, operating results and prospects. Furthermore, some of these suppliers are smaller companies. To the extent that any of these suppliers are, or become, undercapitalized and do not otherwise have sufficient resources to continue operations or to supply us sufficient product without additional access to capital, such a failure could adversely affect our business. We also may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, the competent authorities or notified bodies of the Member States of the EEA, or foreign regulatory authorities and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Furthermore, since many of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments of components to us. For example, all foreign importers of medical devices are required to meet applicable FDA requirements, including registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events, and premarket notification 510(k) clearance or PMA, if applicable. In addition, all imported medical devices also must meet Bureau of Customs and Border Protection requirements. While it is our policy to maintain sufficient inventory of materials and components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials.

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

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

- the number and mix of products sold in the quarter and the geographies in which they are sold;
- the demand for, and pricing of, our products and the products of our competitors;
- the timing of or failure to obtain regulatory clearances or approvals for products;
- costs, benefits and timing of new product introductions;
- the level of competition;
- the timing and extent of promotional pricing or volume discounts;

changes in average selling prices;

the availability and cost of components and materials;

the number of selling days;

fluctuations in foreign currency exchange rates

the timing of patients use of their calendar year medical insurance deductibles; and

impairment and other special charges.

Table of Contents

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;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize new products or product candidates.

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

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

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

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

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

As a result of the need to maintain substantial levels of inventory and instruments, we are subject to the risk of obsolescence. The nature of our business requires us to maintain a substantial level of inventory and instruments. For example, our total consolidated inventory balances were

$81.4 million and $79.9 million at September 30, 2012 and January 1, 2012, respectively, and our total consolidated instrument balances were $48.5 million and $49.3 million at September 30, 2012 and January 1, 2012, 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.

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

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

Table of Contents

difficulties in integrating OrthoHelix and its personnel and products, as well as the personnel and products of any other acquired companies, into our existing business;

difficulties in integrating OrthoHelix s and Tornier s commercial organizations, including in particular distribution and sales representative arrangements;

difficulties or delays in realizing the anticipated benefits of our acquisition of OrthoHelix or any additional acquired companies and their products;

diversion of our management s time and attention from other business concerns;

challenges due to limited or no direct prior experience in new markets or countries we may enter;

the potential loss of key employees, including in particular sales and research and development personnel, of our company, OrthoHelix or any other business we may acquire;

the potential loss of key customers, distributors, representatives, vendors and other business partners who choose not to do business with our company post-acquisition;

inability to effectively coordinate sales and marketing efforts to communicate our capabilities post-acquisition and coordinate sales organizations to sell our combined products;

inability to successfully develop new products and services on a timely basis that address our new market opportunities post-acquisition;

inability to compete effectively against companies already serving the broader market opportunities expected to be available to us post-acquisition;

difficulties in the assimilation of different corporate cultures, practices and sales and distribution methodologies, as well as in the assimilation and retention of geographically dispersed, decentralized operations and personnel;

unanticipated costs, litigation and other contingent liabilities;

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

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

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

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

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

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

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

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

the possibility that the acquisition may not further our business strategy as we expected;

the possibility that we may not be able to expand the reach and customer base for OrthoHelix s products as expected;

the possibility that we may not be able to expand the reach and customer base for our products as expected; and

the fact that the acquisition will substantially expand our lower extremity joints and trauma business, and we may not experience anticipated growth in that market.

Table of Contents

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

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

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

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

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

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

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

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

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

- 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.

Table of Contents

We believe that our cash and cash equivalents balance of $58.5 million as of September 30, 2012 (which has subsequently been reduced due to the acquisition of OrthoHelix and retirement of our indebtedness outstanding prior to that acquisition), anticipated cash receipts generated from revenue of our products and available credit under our new $30 million senior secured revolving credit facility, will be sufficient to meet our anticipated cash requirements for the remainder of 2012. However, our future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the scope, rate of progress and cost of our clinical trials;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the cost of defending any claims of product liability, or other claims against us, such as contract liabilities;
- the cost and timing of additional regulatory clearances or approvals;
- the cost and timing of expanding our sales, marketing and distribution capabilities;
- the cost and timing of expanding our product offering inventories;
- our ability to collect amounts receivable from customers;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in additional businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

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

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

Although we believe that our anticipated operating cash flows, on-hand cash levels and access to credit will give us the ability to meet our financing needs for at least the next 12 months, there can be no assurance that they will do so. The lack of the borrowing availability under our revolving credit facility and our potential inability to obtain replacement sources of credit could materially affect our operations and financial condition.

Table of Contents

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

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

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

A failure to comply with the covenants and other provisions of our credit agreement could result in events of default under such agreement, which could require the immediate repayment of our outstanding indebtedness. If we are at any time unable to generate sufficient cash flows from operations to service our indebtedness when payment is due, we may be required to attempt to renegotiate the terms of the agreements relating to the indebtedness, seek to refinance all or a portion of the indebtedness or obtain additional financing. There can be no assurance that we will be able to successfully renegotiate such terms, that any such refinancing would be possible or that any additional financing could be obtained on terms that are favorable or acceptable to us.

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

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

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

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

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

We operate through multiple entities and in multiple income tax jurisdictions with different income tax rates both inside and outside the United States and the Netherlands. Accordingly, our management must determine the appropriate allocation of income to each such entity and each of these jurisdictions. Income tax audits associated with the allocation of this income and other complex issues, including inventory transfer pricing and cost sharing and product royalty arrangements, may require an extended period of time to resolve and may result in income tax adjustments

if changes to the income allocation are required. Since income tax adjustments in certain jurisdictions can be significant, our future operating results could be negatively impacted by settlement of these matters.

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

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

Table of Contents

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

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

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

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

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

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

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or operating results.

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

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, purchasing and inventory management. Currently, we have a non-interconnected information technology system; however, we have undertaken planning for the implementation of an upgrade of our systems, which could include the implementation of a new global enterprise resource planning system (ERP). We expect that this upgrade will take two to three years to implement; however, when complete it should enable management to better and more efficiently conduct our operations and gather, analyze, and assess information across all of our business and geographic locations. This upgrade will require the investment of significant human and financial resources. We may experience difficulties in implementing this upgrade in our business operations, or difficulties in

39

Table of Contents

operating our business under this upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain, and otherwise adequately service our customers, and lead to increased costs and other difficulties. In the event we experience significant disruptions as a result of this implementation of an upgraded information technology system, we may not be able to fix our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our operating results and cash flows.

Risks Related to Regulatory Environment

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

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

- design, development and manufacturing;
- testing, labeling, packaging, content and language of instructions for use, and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;
- recordkeeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; and
- product import and export.

Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or PMA, from the FDA, unless an exemption

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

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

Table of Contents

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

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

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

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

To market and sell our products in other countries, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals, certifications

or registrations are expensive, and we cannot be certain that we will receive regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

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

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

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

Table of Contents

additional clearances or approvals. No assurance can be given that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA. If the FDA requires us to cease marketing and recall the modified device until we obtain a new 510(k) clearance or PMA, our business, financial condition, operating results and future growth prospects could be materially adversely affected. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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.

Table of Contents

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

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

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;

withdrawing 510(k) clearances or PMAs that have already been granted;

refusal to grant export approval for our products; or

criminal prosecution.

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

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

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

imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

delaying the introduction of our new products into the market;

recalling or seizing our products;

withdrawing, delaying or denying approvals or clearances for our products;

issuing warning letters or untitled letters;

imposing operating restrictions;

imposing injunctions; and

commencing criminal prosecutions.

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false

statements relating to healthcare matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information; and

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.

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

47

Table of Contents

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

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

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

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

Risks Related to Our Intellectual Property

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

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. The patents we own may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes that are similar to ours. In addition, we cannot be certain that any of our pending patent applications will be issued. The USPTO may reject or require a significant narrowing of the claims in our pending patent applications affecting the patents issuing

Table of Contents

from such applications. Any patents issuing from the pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO and the proceedings may be time-consuming, which may cause significant diversion of effort by our technical and management personnel. These proceedings could result in adverse decisions as to the validity of our inventions and may result in the narrowing or cancellation of claims in issued patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as U.S. laws or at all. We also may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

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

In addition, there are numerous recent changes to the U.S. patent laws and proposed changes to the rules of the USPTO, which may have a significant impact on our ability to obtain and enforce intellectual property rights. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was adopted in September 2011. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. Under the Leahy-Smith Act, the U.S. is transitioning from a first-to-invent system to a first-to-file system for patent applications filed on or after March 16, 2013. With respect to patent applications filed on or after March 16, 2013, if we are the first to invent but not the first to file a patent application, we may not be able to fully protect our intellectual property rights and may be found to have violated the intellectual property rights of others if we continue to operate in the absence of a patent issued to us. The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until up to 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

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

49

Table of Contents

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.

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

Risks Relating to Our Ordinary Shares

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

The trading volume and prices of our ordinary shares have been and may continue to be volatile and could fluctuate widely due to factors beyond our control. Since our initial public offering in February 2011, the sale price of our ordinary shares has ranged from $16.58 per share to $29.93 per share, as reported by the NASDAQ Global Select Market. This may happen because of broad market and industry factors, like the performance and fluctuation of the market prices of other companies with business operations located mainly in Europe that have listed their securities in the United States. In addition to market and industry factors, the price and trading volume for our ordinary shares may be highly volatile for factors specific to our own operations, including the following:

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

Any of these factors may result in large and sudden changes in the volume and price at which our ordinary shares trade. In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company s securities. If we were involved in a class action suit, it could divert a significant amount of our management s attention and other

resources from our business and operations, which could harm our operating results and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect on our financial condition and operating results.

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

Table of Contents

statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for fiscal 2009, we identified a material weakness in our internal control over financial reporting relating to our audited financial statements for fiscal 2007 and fiscal 2008. Specifically, in our case, management and our independent registered accounting firm determined that internal controls over identifying, evaluating and documenting accounting analysis and conclusions over complex non-routine transactions, including related-party transactions, required strengthening. Although we remediated this material weakness, additional control deficiencies may be identified by management or our independent registered public accounting firm, and such control deficiencies also could represent one or more material weaknesses. A report by us of a material weakness may cause investors to lose confidence in our financial statements, and the trading price of our ordinary shares may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our ordinary shares may decline.

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

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

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

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

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

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

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

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

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

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

51

Table of Contents

We do not anticipate paying dividends on our ordinary shares.

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

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

Warburg Pincus (Bermuda) Private Equity IX, L.P. and its affiliates, or Warburg Pincus, beneficially own, in the aggregate, approximately 44% of our outstanding ordinary shares. These shareholders could have an effect on matters requiring our shareholders approval, including the election of directors. This concentration of ownership also may delay, deter or prevent a change in control, and 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Recent Sales of Unregistered Securities

During the third quarter of 2012, we did not issue any ordinary shares or other equity securities of our company that were not registered under the Securities Act of 1933, as amended, other than the 1,941,270 ordinary shares issued to certain shareholders and other equity holders of OrthoHelix in connection with our acquisition of OrthoHelix, as described in more detail in our current report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012.

Use of Proceeds from Initial Public Offering

Our initial public 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 $149.2 million, after underwriters discounts and commissions of approximately $10.8 million and offering related expenses of $6.2 million. 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, and received additional net proceeds of approximately $12.8 million, after underwriters discounts and commissions of approximately $0.9 million. Aggregate gross proceeds from the offering, including the exercise of the over-allotment option, were $180.0 million and net proceeds received after underwriters discounts and commissions and offering related expenses were approximately $162.0 million.

Through September 30, 2012, we used approximately $116.1 million (86.4 million) of the net proceeds from the offering to repay all of the outstanding indebtedness under our notes payable, including accrued interest thereon. Additionally, through September 30, 2012, we used $9.1 million of the net proceeds from the offering to purchase instruments and implants and $16.8 million to reduce our short-term borrowings under our lines of credit. The majority of the $116.1 million used to repay the outstanding indebtedness under our notes payable, including accrued interest thereon, and none of the $9.1 million used to purchase instruments and implants or $16.8 million used to reduce our short-term borrowings under our various lines of credit were paid to certain of our directors and officers, or their associates, to persons owning ten percent or more of our outstanding ordinary shares and other affiliates of ours.

Table of Contents

We expect to use the remaining net proceeds for general corporate purposes. Pending the uses described above, we have invested the remaining net proceeds in a variety of short-term, interest-bearing, time deposits. There has been no material change in the 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).

Issuer Purchases of Equity Securities

We did not purchase any ordinary shares or other equity securities of ours during the third quarter of 2012.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable.

ITEM 6. EXHIBITS.

The following exhibits are filed or furnished with this quarterly report on Form 10-Q:

Exhibit No.	Description
2.1*	Agreement and Plan of Merger dated as of August 23, 2012 by and among Tornier N.V., Oscar Acquisition Corp., OrthoHelix Surgical Designs, Inc. and the Representative (Incorporated by reference to Exhibit 2.1 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-35065))
10.1	Credit Agreement dated as of October 4, 2012 among Tornier N.V., Tornier, Inc., as Borrower, Bank of America, N.A., as Administrative Agent, SG Americas Securities, LLC, as Syndication Agent, BMO Capital Markets and JPMorgan Chase Bank, N.A., as Co-Documentation Agents, Merrill Lynch, Pierce, Fenner & Smith Incorporated and SG Americas Securities, LLC, as Joint Lead Arrangers and Joint Bookrunners, and the Other Lenders Party Thereto (Incorporated by reference to Exhibit 10.1 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-35065))
10.2	Offer Letter between Tornier, Inc. and Shawn T McCormick (Incorporated by reference to Exhibit 10.1 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2012 (File No. 001-35065))
10.3	Form of Employment Agreement between Tornier, Inc. and Shawn T McCormick (Incorporated by reference to Exhibit 10.2 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2012 (File No. 001-35065))
10.4	Form of Indemnification Agreement between Tornier N.V. and its executive officers (incorporated by reference to Exhibit 10.40 to Tornier s Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 14, 2010 (Registration No. 333-167370))
10.5	Separation Agreement and Release of Claims effective as of July 17, 2012 between Tornier, Inc. and Carmen L. Diersen (Incorporated by reference to Exhibit 10.4 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2012 (File No. 001-35065))
10.6	Consulting Agreement effective as of July 17, 2012 between Tornier, Inc. and Carmen L. Diersen (Incorporated by reference to Exhibit 10.5 to Tornier s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2012 (File No. 001-35065))

10.7	Rider No. 1 to the Commercial Lease dated February 6, 2008 dated August 18, 2012 between Balux SCI and Tornier SAS (Filed herewith)
10.8	Rider No. 1 to Commercial Lease dated August 18, 2012 between Animus SCI and Tornier SAS (Filed herewith)
31.1	Certification of Chief Executive Officer Pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
31.2	Certification of Chief Financial Officer Pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)

Table of Contents

Exhibit No.	Description
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
101	The following materials from Tornier N.V. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets as of September 30, 2012 and January 1, 2012, (ii) the unaudited Consolidated Statements of Operations for the three and nine months ended September 30, 2012, (iii) the unaudited Consolidated Statements of Comprehensive (Loss) Income for the three and nine months ended September 30, 2012, (iv) the unaudited Consolidated Statements of Cash Flows for the nine months ended September 30, 2012, and (v) Notes to Consolidated Financial Statements (Furnished herewith)**

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

** Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this quarterly report on Form 10-Q shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under Section 11 or 12 of the Securities Act of 1933, as amended, or otherwise subject to the liability of those sections, except as shall be expressly set forth by specific reference in such filings.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TORNIER N.V.

Date: November 9, 2012

By: /s/ Douglas W. Kohrs
Douglas W. Kohrs
President, Chief Executive Officer
(principal executive officer)

By: /s/ Shawn T McCormick
Shawn T McCormick
Global Chief Financial Officer
(principal financial and accounting officer)

Table of Contents

TORNIER N.V.

QUARTERLY REPORT ON FORM 10-Q

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