Tornier N.V.
Form 10-Q
November 06, 2013
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 29, 2013

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	**(I.R.S. Employer**
Incorporation or Organization)	**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 x
Non-accelerated filer ¨ (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 1, 2013, there were 48,480,336 ordinary shares outstanding.

Table of Contents

TORNIER N.V.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 29, 2013

TABLE OF CONTENTS

References to Tornier, Company, we, our or us in this report refer to Tornier N.V. and its subsidiaries, unless the context otherwise requires.

This report contains references to among others, our trademarks Aequalis®, Aequalis Ascend®, Aequalis Ascend Flex , Latitude®, Salto Talaris®, Simpliciti , Conexa , BioFiber®, 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, pre estimate or continue, other words and terms of similar meaning and the use of future dates. These forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially from those matters expressed or implied by our forward-looking statements. Forward-looking statements (including oral representations) are only predictions or statements of current plans and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including, among other things, risks associated with:

- our history of operating losses and negative cash flow;

- 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, transitions to direct selling models in certain geographies, including most recently in Canada, Australia, Japan, Belgium and Luxembourg and in the United States, and the transition of our U.S. sales channel towards focusing separately on upper and lower extremity products, and the adverse impact of such changes and transitions on our revenue and other operating results;

- 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;

- continuing weakness in the global economy, which has been and may continue to be exacerbated by austerity measures taken by several countries, and automatic and discretionary governmental spending cuts, which could reduce the availability or affordability of private insurance or Medicare or other governmental reimbursement 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, including in particular France, and risks and uncertainties involved in launching our products in certain new geographic markets, including in particular Japan and China;

our reliance on sales of our upper extremity joints and trauma products, including in particular our shoulder products, which generate a significant portion of our revenue, and the recent launch of our Aequalis Ascend Flex;

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;

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

not successfully competing against our existing or potential competitors;

changes in our senior management;

our facilities consolidation in 2012 and its effect on our business and operating results, and our failure to realize anticipated benefits and cost savings;

our credit agreement, senior secured term loan and revolving credit facility and risks related thereto;

the reliance of our business plan on certain market assumptions;

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

Table of Contents

our patents and other intellectual property rights not adequately protecting our products or alleged claims of patent infringement by us, which may result in our loss of market share to our competitors and increased expenses;

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 credit agreement that may limit our operating flexibility;

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

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, including the excise tax on U.S. sales of certain medical devices, and its 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, which could have an adverse effect on our business, financial condition or operating results.

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 Other Information Item 1A. Risk Factors of this report. The risks and uncertainties described above and under the heading Part II Other Information 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 29, 2013 (unaudited)	December 30, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 62,552	$ 31,108
Accounts receivable (net of allowance of $4,668 and $4,846, respectively)	48,633	54,192
Inventories	84,584	86,697
Income taxes receivable		382
Deferred income taxes	2,774	2,734
Prepaid taxes	15,148	14,752
Prepaid expenses	3,185	2,998
Other current assets	3,349	4,455
Total current assets	220,225	197,318
Instruments, net	58,657	51,394
Property, plant and equipment, net	41,797	37,151
Goodwill	247,708	239,804
Intangible assets, net	119,697	126,594
Deferred income taxes	151	159
Other assets	2,496	1,807
Total assets	$ 690,731	$ 654,227
Liabilities and shareholders equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	$ 1,229	$ 4,595
Accounts payable	13,862	11,526
Accrued liabilities	46,306	44,410
Income taxes payable	874	83
Contingent consideration, current	7,703	
Deferred income taxes	13	12
Total current liabilities	69,987	60,626
Long-term debt	66,070	115,457
Deferred income taxes	20,705	20,284

Contingent consideration, long-term	4,539	15,265
Other non-current liabilities	6,093	6,516
Total liabilities	167,394	218,148
Shareholders equity:		
Ordinary shares, 0.03 par value; authorized 175,000,000; issued and outstanding 48,401,499 and 41,728,257 at September 29, 2013 and December 30, 2012, respectively	1,916	1,655
Additional paid-in capital	764,293	660,968
Accumulated deficit	(261,457)	(235,732)
Accumulated other comprehensive income	18,585	9,188
Total shareholders equity	523,337	436,079
Total liabilities and shareholders equity	$ 690,731	$ 654,227

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 29, 2013	September 30, 2012	September 29, 2013	September 30, 2012
	(unaudited)		(unaudited)	
Revenue	$ 66,747	$ 58,015	$ 227,567	$ 198,487
Cost of goods sold	18,972	15,730	64,905	54,944
Gross profit	47,775	42,285	162,662	143,543
Operating expenses (income):				
Selling, general and administrative	46,797	38,524	150,400	124,157
Research and development	4,665	5,260	16,390	16,329
Amortization of intangible assets	3,976	2,730	11,597	8,013
Special charges	(3,918)	6,503	1,009	9,413
Total operating expenses	51,520	53,017	179,396	157,912
Operating loss	(3,745)	(10,732)	(16,734)	(14,369)
Other income (expense):				
Interest income	85	70	181	304
Interest expense	(1,499)	(481)	(5,754)	(1,430)
Foreign currency transaction loss	(285)	(326)	(1,071)	(195)
Loss on extinguishment of debt			(1,127)	
Other non-operating income	95	56	183	54
Loss before income taxes	(5,349)	(11,413)	(24,322)	(15,636)
Income tax expense	(943)	(268)	(1,405)	(1,305)
Consolidated net loss	$ (6,292)	$ (11,681)	$ (25,727)	$ (16,941)
Net loss per share:				
Basic and diluted	$ (0 .13)	$ (0.29)	$ (0.57)	$ (0.43)
Weighted average shares outstanding:				
Basic and diluted	48,068	39,708	44,942	39,537

TORNIER N.V. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

	Three months ended		Nine months ended	
	September 29, 2013	September 30, 2012	September 29, 2013	September 30, 2012
Consolidated net loss	$ (6,292)	$ (11,681)	$ (25,727)	$ (16,941)
Foreign currency translation adjustments	9,324	6,395	9,397	147
Comprehensive income (loss)	$ 3,032	$ (5,286)	$ (16,330)	$ (16,794)

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 29, 2013	**September 30, 2012**
	(unaudited)	
Cash flows from operating activities:		
Consolidated net loss	$ (25,727)	$ (16,941)
Adjustments to reconcile consolidated net loss to cash provided by operating activities:		
Depreciation and amortization	26,803	21,398
Impairment of fixed assets		1,028
Lease termination costs		731
Non-cash foreign currency loss (gain)	1,079	(217)
Deferred income taxes	1,929	(147)
Share-based compensation	4,753	5,108
Non-cash interest expense and discount amortization	756	
Inventory obsolescence	6,382	2,913
Loss on extinguishment of debt	1,127	
Incentive related to new facility lease		703
Acquired inventory step-up	5,445	
Gain on reversal of OrthoHelix contingent consideration liability	(4,947)	
Other non-cash items affecting earnings	619	1,441
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable	5,400	4,533
Inventories	(5,842)	(3,474)
Accounts payable and accruals	311	(3,429)
Other current assets and liabilities	2,403	(1,317)
Other non-current assets and liabilities	(2,170)	(1,194)
Net cash provided by operating activities	18,321	11,136
Cash flows from investing activities:		
Acquisition-related cash payments	(5,672)	(2,246)
Purchases of intangible assets	(2,086)	(1,410)
Additions of instruments	(16,565)	(9,245)
Property, plant and equipment lease incentive		(1,020)
Purchases of property, plant and equipment	(7,518)	(6,866)
Net cash used in investing activities	(31,841)	(20,787)
Cash flows from financing activities:		

Change in short-term debt	(1,000)	9,350
Repayments of long-term debt	(53,688)	(8,233)
Proceeds from issuance of long-term debt		5,172
Deferred financing costs	(111)	
Issuance of ordinary shares from stock option exercises	19,983	7,108
Proceeds from issuance of ordinary shares	78,870	
Net cash provided by financing activities	44,054	13,397
Effect of exchange rate changes on cash and cash equivalents	910	47
Increase in cash and cash equivalents	31,444	3,793
Cash and cash equivalents:		
Beginning of period	31,108	54,706
End of period	$ 62,552	$ 58,499
Non-cash investing and financing activities:		
Fixed assets acquired pursuant to capital lease	$ 42	$ 359
Capitalized software development costs	1,357	

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 100 product lines in approximately 40 countries.

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 December 30, 2012, as filed with the U.S. Securities and Exchange Commission (SEC).

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 and ends 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 third quarters of 2013 and 2012 each consisted of 13 weeks.

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.

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

Recent Accounting Pronouncement

The Company adopted Accounting Standards Update (ASU) 2013-02, Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. ASU 2013-02 amended Accounting Standards Codification (ASC) 220 to require companies to report, in one place, information about reclassifications out of accumulated other comprehensive income (AOCI). The ASU allows companies to present this information on the face of the financial statements, if certain requirements are met. Otherwise, the information must be presented in the notes. The ASU requires information about the effect (i.e., amount) of significant reclassification items on the line items of net income by component of other comprehensive income (OCI). In addition, the ASU requires detailed reporting about changes in AOCI balances. It requires companies to present details of current-period changes in AOCI on the face of the financial statements or in the notes. The adoption of this standard did not have a material impact for the Company in the first nine months of 2013.

Table of Contents

In July 2013, the FASB issued ASU No. 2013-11, Income Taxes (ASU No. 2013-11). ASU No. 2013-11 requires companies to present unrecognized tax benefits as a reduction of the deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, if net settlement is required or expected. To the extent that net settlement is not required or expected, the unrecognized tax benefit must be presented as a liability. The assessment of whether a deferred tax asset is available is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date and should be made presuming disallowance of the tax position at the reporting date. ASU No. 2013-11 is effective for reporting periods beginning after December 15, 2013, and should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Because this standard only affects the presentation of unrecognized tax benefits and not the measurement of an unrecognized tax benefit, the Company expects this standard will not have a material impact on its consolidated financial statements.

3. Business Combination

On October 4, 2012, the Company completed the acquisition of 100% of the outstanding capital stock of OrthoHelix Surgical Designs, Inc. (OrthoHelix). OrthoHelix is a company that is 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. Under the terms of the agreement, the Company acquired the assets and assumed certain liabilities of OrthoHelix for an aggregate purchase price of $152.6 million, including $100.4 million in cash, the equivalent of $38.0 million in Tornier ordinary shares based on the closing share price on the date of acquisition, and $14.2 million related to the fair value of additional contingent consideration of up to $20.0 million. The contingent consideration is payable in future periods based on growth of the Company s lower extremity joints and trauma revenue category in fiscal years 2013 and 2014.

The OrthoHelix acquisition was accounted for as an acquisition of a business; and, accordingly, the results have been included in the Company s consolidated results of operations from the date of acquisition. The allocation of the total purchase price to the net tangible and identifiable intangible assets was based on their estimated fair values as of the acquisition date. The excess of the purchase price over the identifiable intangible and net tangible assets in the amount of $105.8 million was allocated to goodwill, which is not deductible for tax purposes. Qualitatively, the three largest components of goodwill include: (1) expansion into international markets; (2) the relationships between the Company s sales representatives and physicians; and (3) the development of new product lines and technology. During the first quarter of 2013, the Company finalized the purchase accounting for this transaction and recorded minor adjustments to accounts receivable and goodwill.

The following represents the allocation of the purchase price, along with the estimated useful lives of the identified intangible assets:

	Purchase price allocation (in thousands)	Estimated useful life
Goodwill	$ 105,791	
Other intangible assets		
Developed technology	$ 35,500	10
In-process research and development	3,500	N/A
Trademarks and trade names	1,500	3
Non-compete agreements	100	3

Tangible assets acquired and liabilities assumed:		
Accounts receivable		4,443
Inventory		12,033
Other assets		776
Instruments, net		4,475
Accounts payable and accrued liabilities		(3,606)
Deferred income taxes		(11,900)
Other long-term debt		(16)
Total purchase price	$	152,596

The Company s acquisition of OrthoHelix involves the potential for the payment of future contingent consideration upon the achievement of certain product revenue growth milestones. Contingent consideration is recorded at the estimated fair value of the contingent milestone payments on the acquisition date. The fair value of the contingent milestone consideration is remeasured at the estimated fair value at each reporting period with the change in fair value recognized as income or expense within operating expenses in the consolidated statements of operations.

Table of Contents

At September 29, 2013, the fair value of the contingent consideration was $10.3 million and was determined based on a discounted cash flow analysis that included revenue estimates and a discount rate, which are considered significant unobservable inputs. The revenue estimates were based on current management expectations for the business and the discount rate used as of September 29, 2013 was 7.5% based on the Company s estimated weighted average cost of capital.

Pro forma results of operations (unaudited) of the Company for the nine months ended September 30, 2012, as if the acquisition had occurred on January 2, 2012, are as follows:

	Nine months ended September 30, 2012
Revenue	$ 219,017
Net loss	(25,011)
Basic and diluted net loss per share	$ (0.60)

The pro forma results of operations are not necessarily indicative of future operating results. Included in the consolidated statement of operations for the nine months ended September 29, 2013 is approximately $24.5 million of revenue and $0.7 million of net loss related to OrthoHelix.

4. Fair Value of Financial Instruments

The Company applies ASC Topic 820, which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. 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.

A summary of the financial assets and liabilities that are measured at fair value on a recurring basis at September 29, 2013 and December 30, 2012 are as follows:

	September 29, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$ 62,552	$ 62,552	$	$
Contingent consideration	(12,242)			(12,242)

Derivative asset	117		117	
Total, net	$ 50,427	$ 62,552	$ 117	$ (12,242)

	December 30, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$ 31,108	$ 31,108	$	$
Contingent consideration	(15,265)			(15,265)
Derivative asset	274		274	
Total, net	$ 16,117	$ 31,108	$ 274	$ (15,265)

As of September 29, 2013 and December 30, 2012, the Company had a derivative asset with a fair value of $0.1 million and $0.3 million, respectively, with recurring Level 2 fair value measurements. The derivatives are foreign exchange forward contracts and their fair values are based on pricing for similar recently executed transactions. The contracts were first entered into in 2012. The amount of gain (loss) recognized in foreign exchange gain (loss) for the nine months ended September 29, 2013 and September 30, 2012 related to this derivative is approximately $0.1 million and $(0.1) million, respectively. Included in Level 3 fair value

Table of Contents

measurements as of September 29, 2013 are the following: a $0.5 million contingent consideration liability related to potential earn-out payments for the acquisition of the Company s exclusive distributor in Belgium and Luxembourg that was completed in May 2012, a $10.3 million contingent consideration liability related to potential earn-out payments for the acquisition of OrthoHelix that was completed in October 2012, and a $1.4 million contingent consideration liability related to earn-out payments for distributor acquisitions in the United States that occurred throughout the first nine months of 2013. Earn-out liabilities are carried at fair value and included in contingent consideration (short term and long term) on the consolidated balance sheet. The earn-out liabilities related to the Company s distributor in Belgium and Luxembourg, OrthoHelix, and the U.S. distributors were determined based on discounted cash flow analyses that included revenue estimates and a discount rate, which are considered significant unobservable inputs as of September 29, 2013. The revenue estimates were based on current management expectations for these businesses and the discount rate used was between 8-14% and was based on the Company s estimated weighted average cost of capital as adjusted for each transaction. To the extent that these assumptions were to change, the fair value of the contingent consideration liabilities could change significantly. Included in interest expense on the consolidated statement of operations for the nine months ended September 29, 2013 is $0.8 million related to the accretion of the contingent consideration. There were no transfers between levels during the nine months ended September 29, 2013.

Included in Level 3 fair value measurements as of December 30, 2012 is a $0.7 million contingent consideration liability related to potential earn-out payments for the acquisition of the Company s exclusive distributor in Belgium and Luxembourg that was completed in May 2012 and a $14.5 million contingent consideration liability related to potential earn-out payments for the acquisition of OrthoHelix that was completed in October 2012. The contingent consideration liabilities are carried at fair value, which is determined based on a discounted cash flow analysis that included revenue estimates and a discount rate, which are considered significant unobservable inputs as of December 30, 2012. The revenue estimates were based on then current management expectations for these businesses and the discount rate used as of December 30, 2012 was 8% and was based on the Company s estimated weighted average cost of capital. Included in interest expense on the consolidated statement of operations for the nine months ended September 30, 2012 is $0.1 million related to the accretion of the contingent consideration. There were no transfers between levels during the nine months ended September 29, 2013.

The Company also has certain 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 quarters ended September 29, 2013 and September 30, 2012, the Company recognized no impairments. During 2012, the Company initiated and completed a facilities consolidation initiative that included the termination of certain facility leases. The termination liability for these leases was 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. The timing of the sublease income is a significant unobservable input and thus is considered a Level 3 fair value measurement. As of September 29, 2013, the value of this liability was approximately $0.4 million.

As of September 29, 2013, the Company had short-term and long-term debt of $67.3 million, the vast majority of which was variable rate debt. The fair value of the Company s debt obligations approximates carrying value as a result of its variable rate term and is considered a Level 2 fair value measurement.

5. Inventories

Inventory balances consist of the following (in thousands):

	September 29, 2013	December 30, 2012
Raw materials	$ 6,435	$ 5,696
Work-in-process	6,640	4,933
Finished goods	71,509	76,068
Total	$ 84,584	$ 86,697

Table of Contents

6. Property, Plant and Equipment

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

	September 29, 2013	December 30, 2012
Land	$ 1,848	$ 1,830
Building and improvements	14,027	12,908
Machinery and equipment	29,007	25,767
Furniture, fixtures and office equipment	29,208	26,541
Software	5,194	4,729
Construction in progress	4,223	2,148
Property, plant, and equipment, gross	83,507	73,923
Accumulated depreciation	(41,710)	(36,772)
Property, plant and equipment, net	$ 41,797	$ 37,151

7. Instruments

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

	September 29, 2013	December 30, 2012
Instruments	$ 97,786	$ 85,869
Instruments in process	21,859	18,171
Accumulated depreciation	(60,988)	(52,646)
Instruments, net	$ 58,657	$ 51,394

8. Goodwill and Other Intangible Assets

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

Balance at December 30, 2012	$ 239,804
Acquisition related additions	5,896
Foreign currency translation	2,008
Balance at September 29, 2013	$ 247,708

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

	Gross value	Accumulated amortization	Net value
Balances at September 29, 2013			
Intangible assets subject to amortization:			
Developed technology	$ 110,432	$ (41,443)	$ 68,989
Customer relationships	60,789	(28,512)	32,277
Licenses	6,780	(3,617)	3,163
In-process research and development	2,000		2,000
Other	5,541	(2,028)	3,513
Intangible assets not subject to amortization:			
Trade name	9,755		9,755
Total	$ 195,297	$ (75,600)	$ 119,697

Table of Contents

	Gross value	Accumulated amortization	Net value
Balances at December 30, 2012			
Intangible assets subject to amortization:			
Developed technology	$ 108,274	$ (34,114)	$ 74,160
Customer relationships	59,212	(24,634)	34,578
Licenses	5,525	(2,927)	2,598
In-process research and development	3,200		3,200
Other	3,923	(1,357)	2,566
Intangible assets not subject to amortization:			
Trade name	9,492		9,492
Total	$ 189,626	$ (63,032)	$ 126,594

Estimated annual amortization expense for fiscal years ending 2013 through 2017 is as follows (in thousands):

	Amortization expense
2013	$ 15,499
2014	15,854
2015	15,547
2016	13,934
2017	13,037

During the nine months ended September 29, 2013, the Company acquired certain assets of its distributor in Canada for $3.3 million, which included $0.5 million in potential earn-out payments, which were subsequently paid. The preliminary purchase accounting for this transaction resulted in an increase in intangible assets of $0.5 million, in the form of customer relationships and non-compete agreements, and goodwill of $0.3 million. Additionally, during the nine months ended September 29, 2013, the Company acquired certain assets of a distributor in the United Kingdom for $1.2 million, which included $0.3 million in potential earn-out payments, which were subsequently paid. The preliminary purchase accounting for this transaction resulted in an increase in intangible assets of $0.1 million in the form of customer relationships. Also during the nine months ended September 29, 2013, the Company acquired intangible assets in the form of non-compete agreements valued at $0.6 million and $5.7 million of goodwill related to acquisitions of certain U.S. distributors and independent sales agencies.

9. Debt

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

	September 29, 2013	December 30, 2012
Line of credit	$	$ 1,000
Mortgages	3,308	3,719
Bank term debt	61,722	113,135
Shareholder debt	2,269	2,198

Total debt	67,299	120,052
Less current portion	(1,229)	(4,595)
Long-term debt	$ 66,070	$ 115,457

Line of Credit

On October 4, 2012, the Company and its U.S. operating subsidiary, Tornier, Inc. (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 includes a senior secured revolving credit facility 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 $30.0 million. Funds available under the revolving credit facility may be used for general corporate purposes. Loans under the revolving credit 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 rate in effect on such day plus 1/2 of 1%, and (iii) the adjusted LIBO rate plus 1%, plus in the case of each of (i)-(iii) above, an applicable

Table of Contents

rate of 2.00% or 2.25% (depending on the Company s total net leverage ratio as defined in the Company s credit agreement), or (b) the applicable adjusted LIBO rate for the relevant interest period plus an applicable rate of 3.00% or 3.25% (depending on the Company s total net leverage ratio), plus the mandatory cost (as defined in the Company s credit agreement) if such loan is made in a currency other than U.S. dollars or from a lending office in the United Kingdom or a participating member state (as defined in the Company s credit agreement). There was no outstanding amount under the line of credit as of September 29, 2013. As of December 30, 2012, the outstanding balance related to this line of credit was $1.0 million. The term of the line of credit ends in October 2017.

Mortgages

The Company has a mortgage secured by an office building in Grenoble, France. This mortgage had an outstanding balance of $3.3 million and $3.7 million at September 29, 2013 and December 30, 2012, respectively. This mortgage bears a fixed annual interest rate of 4.9%.

Bank Term Debt

In addition to the senior secured revolving credit facility discussed above, the credit agreement entered into on October 4, 2012 also provided for an aggregate credit commitment to Tornier USA of $115.0 million of term debt, consisting of: (1) a senior secured term loan facility to Tornier USA denominated in U.S. dollars in an aggregate principal amount of up to $75.0 million; and (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 $40.0 million. The borrowings under the term loan facilities were used to pay the cash consideration for the OrthoHelix acquisition, 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 term debt matures in October 2017. In the second quarter of 2013, the $40.0 million senior secured term loan facility denominated in Euros was repaid in full. As part of the repayment, the Company recorded a $1.1 million loss on extinguishment of debt related to the write-off of the corresponding deferred financing costs. Additionally, in June 2013, the Company repaid $10.5 million of the senior secured U.S. dollar denominated loan.

Borrowings under the senior secured term loan facilities within the credit agreement as of September 29, 2013 and December 30, 2012 were as follows:

	September 29, 2013	December 30, 2012
Senior secured U.S. dollar term loan	$ 64,031	$ 75,000
Senior secured Euro term loan		40,772
Deferred financing costs	(3,367)	(5,138)
Total	$ 60,664	$ 110,634

The U.S. dollar denominated term facility bears 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 rate in effect on such day plus 1/2 of 1%, and (iii) the adjusted LIBO rate, with a floor of 1% (as defined in the Company s 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 the Company s total net leverage ratio as defined in the credit agreement), or (b) in the case of a eurocurrency loan (as defined in the Company s credit agreement), at the applicable adjusted LIBO rate for the relevant interest period, with a floor of 1%,

plus an applicable rate of 3.00% or 3.25% (depending on the Company s total net leverage ratio), plus the mandatory cost (as defined in the Company s credit agreement) if such loan is made in a currency other than U.S. dollars or from a lending office in the United Kingdom or a participating member state (as defined in the Company s credit agreement). Under the Euro denominated term facility, (a) alternate base rate loans bear interest at the alternate base rate plus the applicable rate, which was 3.00% or 3.25% (depending on the Company s total net leverage ratio) and (b) eurocurrency loans bear interest at the adjusted LIBO rate for the relevant interest period, with a floor of 1%, plus an applicable rate, which was 4.00% or 4.25% (depending on the Company s total net leverage ratio), plus the mandatory cost, if applicable.

The credit agreement, including the term loan and the revolving line of credit, contains customary covenants, including financial covenants which require the Company to maintain a minimum interest coverage ratio, annual capital expenditure limits and a maximum total net leverage ratio, 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. The Company was in compliance with all covenants as of September 29, 2013.

Table of Contents

The Company s international subsidiaries had other long-term secured and unsecured notes totaling $1.3 million at December 30, 2012, with initial maturities ranging from three to ten years. A portion of these notes have fixed annual interest rates that range from 3.7% to 8.5%.

Also included in term debt is $1.1 million and $1.5 million related to capital leases at September 29, 2013 and December 30, 2012, respectively.

Shareholder Debt

In 2008, one of the Company s 51%-owned and consolidated subsidiaries borrowed $2.2 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. Interest on the debt is variable based on three-month Euro plus 0.5%. The outstanding balance on this debt was $2.3 million and $2.2 million at September 29, 2013 and December 30, 2012, respectively. The non-controlling interest in this subsidiary is deemed immaterial to the consolidated financial statements.

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 generally 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 29, 2013	September 30, 2012 (unaudited)	September 29, 2013	September 30, 2012 (unaudited)
Cost of goods sold	$ 111	$ 206	$ 375	$ 656
Selling, general and administrative	1,448	1,366	3,973	4,139
Research and development	125	141	405	313
Total	$ 1,684	$ 1,713	$ 4,753	$ 5,108

During the nine months ended September 29, 2013, the Company granted 630,739 options to purchase ordinary shares to employees at a weighted average exercise price of $19.37 per share and a weighted average fair value of $8.97 per share. During the nine months ended September 30, 2012, the Company granted 512,610 options to purchase 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. 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 29, 2013
Risk-free interest rate	1.7%
Expected life in years	6.1
Expected volatility	46.6%
Expected dividend yield	0.0%

During the nine months ended September 29, 2013 and September 30, 2012, the Company granted 316,559 and 253,217 restricted stock units, respectively, to employees with a weighted average fair value of $19.30 per share and $18.80 per share, respectively.

Table of Contents

11. Income Taxes

The Company s effective tax rate for the nine months ended September 29, 2013 was 5.8%. During the nine months ended September 29, 2013, the Company recognized $1.4 million of income tax expense on pre-tax losses of $24.3 million. 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 because it has established a valuation allowance for substantially all of the net deferred tax assets in these jurisdictions. The Company records tax expense or benefit in certain other European jurisdictions. The mix of pre-tax income or loss in these jurisdictions as well as in the jurisdictions in which valuation allowances are established are the primary drivers of the Company s effective tax rate. The Company recognized $1.5 million of tax expense in certain of its European jurisdictions during the nine months ended September 29, 2013, but this was offset by a tax benefit of $0.1 million recognized from the reversal of valuation allowance in the United States due to the recognition of deferred tax liabilities related to certain formerly indefinite lived intangible assets that were reclassified to definite lived intangibles during the period. Included in the $1.5 million of tax expense from European jurisdictions is $1.0 million of income tax expense to establish a valuation allowance for deferred tax assets related to foreign stock compensation during the third quarter of 2013. The Company determined the tax planning strategies necessary to realize these deferred tax assets was no longer prudent and as a result the Company no longer believes these deferred tax assets are realizable.

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.

12. Capital Stock and Earnings Per Share

On May 15, 2013, the Company completed an underwritten public offering of 8.1 million ordinary shares at a public offering price of $16.15 per ordinary share. Pursuant to this offering, the Company sold 5.2 million shares and certain shareholders sold 2.9 million shares, both of which were inclusive of the exercise of the underwriters over-allotment option. The Company received $78.9 million in net proceeds from the offering, net of the underwriters discount and commissions and offering expenses. The Company used approximately $50.5 million of the net proceeds to repay its $40.0 million Euro-denominated term loan and a portion of its U.S.-dollar denominated term loan. The Company intends to use the remaining net proceeds for working capital and general corporate purposes.

The Company had 48.4 million and 41.7 million ordinary shares issued and outstanding as of September 29, 2013 and December 30, 2012, respectively.

The Company had options to purchase ordinary shares and RSUs outstanding of an aggregate 3.4 million and 4.2 million at September 29, 2013 and December 30, 2012, respectively. None of the options or RSUs were included in diluted earnings per share for the nine months ended September 29, 2013 and December 30, 2012, respectively, because the Company recorded a net loss in all periods; and therefore, including these instruments would be anti-dilutive.

Table of Contents

13. Special Charges

Special charges are recorded as a separate line item within operating expenses on the consolidated statements of operations and primarily include operating expenses directly related to business combinations and related integration activities, restructuring initiatives (including the facilities consolidation initiative), management exit costs and certain other items that are typically infrequent in nature and that affect the comparability and trend of operating results. The table below summarizes amounts included in special charges (income) for the related periods:

	Nine months ended	
	September 29, 2013	**September 30, 2012**
Acquisition, integration and distributor transition costs	$ 4,742	$ 1,790
Reduction in contingent consideration liability	(4,947)	
Legal settlements	1,214	
Italy bad debt expense		1,995
Facilities consolidation charges		5,254
Management exit costs		374
Total	$ 1,009	$ 9,413

Included in special charges for the nine months ended September 29, 2013 was $4.9 million of gain recognized on the reversal of a contingent consideration liability for OrthoHelix due to updated revenue estimates; $4.7 million of expenses related to acquisition and integration activities of OrthoHelix, U.S. distributor transitions, the Company s acquisition of certain assets of its Canadian distributor and the Company s acquisition of certain assets of a distributor in the United Kingdom; and $1.2 million of expenses related to certain legal settlements.

In the nine months ended September 30, 2012, special charges included $0.4 million 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, $1.8 million of acquisition and integration costs related to the Company s acquisition of OrthoHelix and the Company s exclusive distributor in Belgium and Luxembourg, and $5.3 million of cost related to the Company s facilities consolidation initiative.

The activity in the facility consolidation accrual as of September 29, 2013 was as follows:

Facility consolidation accrual balance as of December 30, 2012	$ 674
Charges:	
Employee termination benefits	
Moving, professional fees and other initiative-related expenses	
Total charges	$
Payments:	
Employee termination benefits	$ (475)

Moving, professional fees and other initiative-related expenses	(107)
Total payments	$ (582)
Facilities consolidation accrual balance as of September 29, 2013	$ 92

Table of Contents

14. Litigation

From time to time, the Company is subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. These actions and proceedings may relate to, among other things, product liability, intellectual property, distributor, commercial and other matters. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where the Company has assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, the Company records the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. The Company discloses a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that material loss may be have been incurred. In the opinion of management, the amount of liability, if any, with respect to these matters, individually or in the aggregate, will not materially affect the Company s consolidated results of operations, financial position or cash flows.

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. At a court-mandated settlement conference on June 7, 2013, the Company settled with each of the parties individually pursuant to which the Company agreed to make a cash payment to each of the two plaintiffs. On that same day, the court issued an order dismissing the case with prejudice effective as of August 9, 2013.

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 , Part II. Other Information Item 1A. Risk Factors and elsewhere in this report. These risks could cause our actual results to differ materially from any future performance suggested below.

Business Overview

We are a global medical device company focused on surgeons that treat musculoskeletal injuries and disorders of the shoulder, elbow, wrist, hand, ankle and foot. We refer to these surgeons as extremity specialists. We sell to this extremity specialist customer base a broad line of joint replacement, trauma, sports medicine and biologic products to treat extremity joints. Our motto of specialists serving specialists encompasses this focus. In certain international markets, we also offer joint replacement products for the hip and knee. We currently sell approximately 100 product lines in approximately 40 countries.

We believe we are differentiated by our full portfolio of upper and lower extremity products, our extremity-focused sales organization and our strategic focus on extremities. We further believe that we are well positioned to benefit from opportunities in the extremity products marketplace, primarily in the shoulder and ankle joint replacement markets and also the foot and ankle trauma market with our October 2012 acquisition of OrthoHelix Surgical Designs, Inc. (OrthoHelix). We believe that the recent launch of our Aequalis Ascend Flex pressed-fit reversed shoulder has further strengthened our market-leading shoulder product portfolio and has expanded our addressable market by filling what we believe was a previous gap in this portfolio. Our principal products are organized in four major categories: upper extremity joints and trauma, lower extremity joints and trauma, sports medicine and biologics, and large joints and other. Our upper extremity joints and trauma products include joint replacement and bone fixation devices for the shoulder, hand, wrist and elbow. Our lower extremity joints and trauma products, which include our OrthoHelix portfolio, include joint replacement and bone fixation devices for the foot and ankle. Our sports medicine and biologics product category includes products used across several anatomic sites to mechanically repair tissue-to-tissue or tissue-to-bone injuries, in the case of sports medicine, or to support or induce remodeling and regeneration of tendons and ligaments, in the case of biologics. Our large joints and other products include hip and knee joint replacement implants and ancillary products. In the United States, we market and sell products from all of our product categories, except large joints. Although we do not actively market hip or knee replacement joints in the United States, we have U.S. Food and Drug Administration (FDA) clearance to sell selected large joint products. Internationally, we sell our full product portfolio in the markets that we serve, including large joints, in select international markets. In addition, as we have received the required regulatory approvals, we have selectively introduced the OrthoHelix product portfolio into certain international markets, including France and Germany, which resulted in the first international sales of these products in the second quarter of 2013.

In the United States, which is the largest orthopaedic market, we believe that our specialists serving specialists market approach is strategically aligned with what we believe is an ongoing trend in orthopaedics for surgeons to specialize in certain parts of the anatomy or certain types of procedures. While we market our products to these extremity specialists, our revenue is generated primarily from sales to healthcare institutions. We historically have had a single sales channel in the United States that consisted of a network of independent commission-based sales agencies, along with direct sales representation in certain territories. Since our acquisition of OrthoHelix, we have been in the process of executing our integration strategy to establish separate U.S. sales channels that are individually focused on the

upper extremity specialist and the lower extremity specialist as we believe that this increased focus will allow us to increase the product proficiency of our sales representatives and increase our selling opportunities by improving our overall procedure coverage, leveraging our entire product portfolio, and accessing new specialists and accounts. To create these separate upper and lower extremity sales channels, we have terminated relationships with certain independent sales agencies and transitioned these territories to new agencies or established direct sales representation; acquired certain sales agencies and established direct sales representation; or transitioned an upper or lower extremity product portfolio between agencies or from an agency to a new direct sales team. During the third quarter of 2013, we made a strategic decision to accelerate these transitions. As a result of these transitions, approximately one-third of our U.S. revenue is now represented by direct sales teams and we expect this to increase to approximately one-half upon completion of this strategic initiative. While we believe that this strategy will make Tornier more competitive, we believe these transitions have resulted in disruption in our U.S. sales channel that adversely affected our revenues during 2012 and the first nine months ended September 29, 2013, and will likely result in further disruption during the remainder of 2013 and into the first half of 2014 as we continue to execute this transition and educate and train the resulting sales teams. As of the end of September 2013, we had completed transitions for dedicated upper and dedicated lower extremities sales coverage in territories representing 61% of our U.S. revenue and anticipate that the transition of the remaining territories will occur in the fourth quarter of 2013. We believe this metric is a key indicator of our U.S. sales channel stability and future U.S. revenue growth potential.

Table of Contents

Internationally, the specialization of surgeons is not as prevalent as it is in the U.S.; and thus, we currently utilize several distribution approaches to serve surgeons and their healthcare institutions depending on individual market needs and requirements. Our international distribution system currently consists of 13 direct sales offices and a network of approximately 25 distributors that sell our products into approximately 40 countries. As part of our strategy to grow internationally, we expanded our distribution and sales efforts into Mexico, Israel, Argentina and Singapore in 2012 and are planning on expanding into Taiwan, Vietnam and the Czech Republic in 2013. In addition, we have selectively transitioned from distributor representation to direct sales representation in certain countries, including the United Kingdom, Denmark, Belgium, Luxembourg, Japan, Canada and Australia, and we have selectively converted from direct sales representation to distributor representation in certain countries, including Spain, during the past few years. We believe that this strategy of international expansion, in combination with the tailoring of our international distribution approach to the needs and requirements of each individual market, could result in additional sales coverage transitions in the future, but that this is necessary to drive the future growth of our business.

In the nine months ended September 29, 2013, we generated revenue of $227.6 million, of which 59% was in the United States and 41% was international.

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 the nine months ended September 29, 2013 and September 30, 2012, approximately 41% and 44% respectively, 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. We, therefore, believe that the risk of a significant impact on our earnings from foreign currency fluctuations is mitigated to some extent.

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.

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. Constant currency growth rates used in the following discussion of results of operations eliminate the impact of period-over-period foreign currency fluctuations. 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 nine months ended September 29, 2013 and September 30, 2012 each consisted of 13 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 29, 2013		September 30, 2012		September 29, 2013		September 30, 2012	
	(in thousands)				(in thousands)			
Statements of Operations Data:								
Revenue	$ 66,747	100%	$ 58,015	100%	$ 227,567	100%	$ 198,487	100%
Cost of goods sold	18,972	28%	15,730	27%	64,905	29%	54.944	28%
Gross profit	47,775	72%	42,285	73%	162,662	71%	143,543	72%
Selling, general and administrative	46,797	70%	38,524	66%	150,400	66%	124,157	63%
Research and development	4,665	7%	5,260	9%	16,390	7%	16,329	8%
Amortization of intangible assets	3,976	6%	2,730	5%	11,597	5%	8,013	4%
Special charges (income)	(3,918)	(6%)	6,503	11%	1,009	0%	9,413	5%
Operating loss	(3,745)	(6%)	(10,732)	(18%)	(16,734)	(7)%	(14,369)	(7)%
Interest income	85	0%	70	0%	181	0%	304	0%
Interest expense	(1,499)	(2%)	(481)	(1%)	(5,754)	(3%)	(1,430)	(1%)
Foreign currency transaction loss	(285)	(0%)	(326)	(1%)	(1,071)	(0%)	(195)	(0%)
Loss on extinguishment of debt		*		*	(1,127)	(0%)		*
Other non-operating income	95	0%	56	0%	183	0%	54	0%
Loss before income taxes	(5,349)	(8%)	(11,413)	(20%)	(24,322)	(11%)	(15,636)	(8%)
Income tax expense	(943)	(1%)	(268)	(0%)	(1,405)	(1%)	(1,305)	(1%)
Consolidated net loss	$ (6,292)	(9%)	$ (11,681)	(20%)	$ (25,727)	(11%)	$ (16,941)	(9%)

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 29, 2013	September 30, 2012	Percent change (as reported)	Percent change (constant currency)	September 29, 2013	September 30, 2012	Percent change (as reported)	Percent change (constant currency)
	($ in thousands)				($ in thousands)			

Upper extremity joints and trauma	$ 40,293	$ 39,429	2%	1%	$ 136,258	$ 129,434	5%	5%
Lower extremity joints and trauma	13,530	5,815	133	133	42,514	19,333	120	120
Sports medicine and biologics	3,117	3,487	(11)	(12)	11,051	11,363	(3)	(3)
Total extremities	56,940	48,731	17	16	189,823	160,130	19	18
Large joints and other	9,807	9,284	6	(1)	37,744	38,357	(2)	(4)
Total	$ 66,747	$ 58,015	15%	13%	$ 227,567	$ 198,487	15%	14%

Revenue by Geography	**Three months ended**				**Nine months ended**			
	September 29, 2013	**September 30, 2012**	**Percent change (as reported)**	**Percent change (constant currency)**	**September 29, 2013**	**September 30, 2012**	**Percent change (as reported)**	**Percent change (at constant currency)**
	($ in thousands)				**($ in thousands) (as reported)**			
United States	$ 40,678	$ 34,377	18%	18%	$ 134,244	$ 110,647	21%	21%
International	26,069	23,638	10	6	93,323	87,840	6	5
Total	$ 66,747	$ 58,015	15%	13%	$ 227,567	$ 198,487	15%	14%

Comparison of three months ended September 29, 2013 to three months ended September 30, 2012

Revenue. Revenue increased by 15% to $66.7 million for the three months ended September 29, 2013 from $58.0 million for the three months ended September 30, 2012, primarily as a result of our acquisition and integration of OrthoHelix and growth in upper

Table of Contents

extremity joints and trauma. Foreign currency exchange rate fluctuations had a positive impact of $0.9 million in the third quarter of 2013 as compared to the same quarter of last year. We believe revenue for the three months ended September 29, 2013 was negatively impacted by disruption in our U.S. sales channel due to our strategic initiative to establish separate sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist.

Revenue by product category. Revenue in upper extremity joints and trauma increased by 2% to $40.3 million for the third quarter of 2013 from $39.4 million for the third quarter of 2012, primarily as a result of the continued increase in revenue from our Aequalis reversed and Aequalis Ascend shoulder product line in our international markets as well as our Latitude elbow product lines, both of which have been widely accepted in the market place. Additionally, revenue for the third quarter of 2013 had a positive impact from foreign currency exchange rates of $0.3 million. We believe that the disruption in our U.S. sales channel negatively impacted upper extremity joints and trauma revenue in the third quarter of 2013, offsetting the growth experienced internationally. This was especially true in certain U.S. territories where our legacy distributor partner relationships were changed. We believe this initiative could continue to negatively impact our revenue for the remainder of 2013 and into 2014 until it is completed. However, we anticipate that revenue from upper extremities will be favorably impacted in future periods as a result of the third quarter of 2013 launch of our Aequalis Ascend Flex shoulder. Revenue in lower extremity joints and trauma increased by 133% to $13.5 million for the third quarter of 2013 from $5.8 million for the third quarter of 2012, primarily as a result of our acquisition and integration of OrthoHelix in the fourth quarter of 2012. This growth was partially offset by decreased revenue of legacy Tornier joint replacement and fixation products due to disruption in our U.S. sales channel. Revenue in sports medicine and biologics decreased 11% to $3.1 million during the third quarter of 2013 compared to $3.5 million in the third quarter of 2012 as growth in our international suture and biologic products was offset by decreases in U.S. sales of Conexa and certain anchor product lines. Revenue from large joints and other increased by 6% to $9.8 million for the third quarter of 2013 from $9.3 million for the third quarter of 2012 primarily from a positive impact from foreign currency exchange rates of $0.6 million. Also impacting revenue from large joints was growth in our core hip product portfolio offset by declines in our sales of our knee products and instrumentation. Revenue from our large joints and other category is primarily generated in certain western European geographies which continued to experience economic pressures, thereby adversely affecting our large joints and other revenue.

Revenue by geography. Revenue in the United States increased by 18% to $40.7 million for the third quarter of 2013 from $34.4 million for the third quarter of 2012, primarily due to revenue from our acquisition and integration of OrthoHelix. Excluding the impact from OrthoHelix, we believe our remaining revenues in the United States decreased as a result of disruption in our U.S. sales channel due to our strategic initiative to establish separate sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist. While we believe this transition will increase our ability to meet our customers needs in the future, it had a negative impact on our United States revenue during the third quarter of 2013 and likely will continue to negatively impact revenue into 2014 until this initiative is complete. International revenue increased by 10% to $26.1 million for the third quarter of 2013 from $23.6 million for the third quarter of 2012. Foreign currency exchange rate fluctuations had a positive $0.9 million impact on international revenue during the third quarter of 2013. International revenue increased due primarily to growth in sales in France and from certain geographic expansion activities in which we increased the number of products sold through direct sales channels in countries where we historically utilized local independent distributor representation. This growth was partially offset by decreases in revenue in certain western European countries due to continued austerity measures and lower procedure volumes and a decrease in revenue in Australia due to the impact of our then pending acquisition of our lower extremity stocking distributor in that country.

Cost of goods sold. Cost of goods sold increased to $19.0 million for the third quarter of 2013 from $15.7 million for the third quarter of 2012. As a percentage of revenue, cost of goods sold increased from 27% for the third quarter of 2012 to 28% for the third quarter of 2013, primarily due to approximately $1.8 million in fair value adjustments

related to inventory acquired in our acquisition of OrthoHelix and our acquisition of our stocking distributor in Canada. Excluding the inventory fair value adjustment items, our cost of goods sold as a percentage of revenue decreased due to product cost improvements, production efficiencies and the insourcing of certain products, partially offset by negative impacts of geographical mix. 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. In addition, the fair value adjustment charges recorded as cost of goods sold from the sell through of inventory acquired from business acquisitions should decline in future periods from the levels experienced in the fourth quarter of 2012 and the first three quarters of 2013 as all fair value adjustment charges related to the OrthoHelix acquired inventory had been recognized as of September 29, 2013.

Selling, general and administrative. Our selling, general and administrative expenses increased by 21% to $46.8 million for the third quarter of 2013 from $38.5 million for the third quarter of 2012. As a percentage of revenue, selling, general and administrative expenses were 70% and 66% for the third quarter of 2013 and the third quarter of 2012, respectively. Included in selling, general and administrative expenses for the third quarter of 2013 is $4.7 million of expense relating to OrthoHelix. Excluding this amount, the increase in total selling, general and administrative expense as a percentage of revenue on a comparable basis quarter over quarter was

Table of Contents

primarily a result of higher non-variable sales expenses due to the establishment of direct sales channels in certain areas of the U.S. and several countries internationally and $0.7 million of expense related to the medical device excise tax in the U.S. We expect selling, general and administrative expenses as a percentage of revenue to be higher than historical levels in the near term until we experience the anticipated revenue benefits of our distribution channel transitions, integration initiatives, investments in sales resources, training and education, and new product launches, including the Aequalis Ascend Flex.

Research and development. Research and development expenses decreased by 11% to $4.7 million for the third quarter of 2013 from $5.3 million for the third quarter of 2012. As a percentage of revenue, research and development expenses decreased 2% to 7% for the third quarter of 2013 from 9% for the third quarter of 2012. The decrease in total research and development expense of $0.6 million was primarily due to the timing of spending on certain projects, partially offset by increases in spending due to our acquisition of OrthoHelix.

Amortization of intangible assets. Amortization of intangible assets increased $1.2 million to $4.0 million for the third quarter of 2013 from $2.7 million for the third quarter of 2012. The increase in amortization expense was primarily attributable to an increase in intangible assets due to our acquisition of OrthoHelix.

Special charges (income). We recorded $(3.9) million in special charges for the third quarter of 2013 compared to $6.5 million for the third quarter of 2012. The $(3.9) million is primarily comprised of a $4.9 million reversal of a contingent consideration liability related to the OrthoHelix acquisition due to the underperformance of legacy Tornier lower extremity products versus established revenue targets offset by $1.1 million of integration costs and distributor transition costs. The $6.5 million of special charges for the quarter ended September 30, 2012 was comprised of approximately $2.7 million of costs incurred in relation to our facilities consolidation initiative, $2.0 million related to bad debt expense in Italy, and $1.8 million of integration costs related to acquisitions. We expect to continue to record special charges during the remainder of 2013 primarily related to the ongoing integration of OrthoHelix and distribution transitions and expect these remaining amounts to range from $0.8 million to $1.8 million. Charges related to the ongoing distribution transitions may continue into 2014 until the U.S. distribution transition initiative is complete.

Interest income. Our interest income was immaterial for both the third quarters of 2013 and 2012.

Interest expense. Our interest expense increased to $1.5 million for the third quarter of 2013 from $0.5 million for the third quarter of 2012 due primarily to the establishment of a new credit facility during the fourth quarter of 2012 which was used to fund our acquisition of OrthoHelix. In addition, interest expense was higher due to the accretion of interest expense related to OrthoHelix earn-out liabilities. We expect to continue to experience interest expense related to our credit agreement; however, in the second quarter of 2013, we repaid our Euro denominated term loan in full and repaid approximately $10.5 million of principal on our U.S. dollar denominated term loan, which should reduce future interest expense from levels incurred in the first half of 2013.

Foreign currency transaction loss. We recognized $0.3 million of foreign currency transaction losses in both the third quarters of 2013 and 2012. 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 was immaterial for both the third quarters of 2013 and 2012.

Income tax expense. Our effective tax rate for the third quarter of 2013 and 2012 was 17.6% and 2.5%, respectively. The change in our effective tax rate from the third quarter of 2012 to the third quarter of 2013 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. In addition, we recorded $1.0 million of income tax expense to establish a valuation allowance for deferred tax assets related to foreign stock compensation during the third quarter of 2013. We determined the tax planning strategies necessary to realize these deferred tax assets was no longer prudent and as a result we no longer believe these deferred tax assets are realizable. We recorded income tax expense of $0.9 million during the third quarter of 2013 compared to income tax expense of $0.3 million for the third quarter of 2012. 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 29, 2013 to the nine months ended September 30, 2012

Revenue. Revenue increased by 15% to $227.6 million for the nine months ended September 29, 2013 from $198.5 million for the nine months ended September 30, 2012, primarily as a result of our acquisition and integration of OrthoHelix and growth in upper extremity joints and trauma. Foreign currency exchange rate fluctuations had a positive impact of $1.2 million in the first nine months

Table of Contents

of 2013. We believe revenue for the nine months ended September 29, 2013 was negatively impacted by disruption in our U.S. sales channel due to our strategic initiative to establish separate sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist.

Revenue by product category. Revenue in upper extremity joints and trauma increased by 5% to $136.3 million for the nine months ended September 29, 2013 from $129.4 million for the nine months ended September 30, 2012, primarily as a result of the continued increase in sales of our Aequalis reversed and Aequalis Ascend shoulder products, with a more significant portion of this growth occurring internationally. We believe that increased sales of our Aequalis reversed shoulder products resulted from continued market movement toward reversed shoulder replacement procedures, while we believe the increase in sales of our Aequalis Ascend shoulder products was due to continued market share gains, both of which were partially offset by decreased revenue from our mature shoulder products and disruption in our U.S. sales channel. Foreign currency exchange rate fluctuations had a positive $0.3 million impact on the upper extremity joints and trauma revenue growth during the nine months ended September 29, 2013. We anticipate that revenue from upper extremity joints and trauma will be favorably impacted in future periods as a result of the third quarter of 2013 launch of our Aequalis Ascend Flex shoulder. Revenue in lower extremity joints and trauma increased by 120% to $42.5 million for the nine months ended September 29, 2013 from $19.3 million for the nine months ended September 30, 2012, primarily as a result of our acquisition and integration of OrthoHelix in the fourth quarter of 2012. This growth was partially offset by decreased revenue of legacy Tornier foot and ankle fixation products due to disruption in our U.S. sales due to our strategic initiative to establish separate sales channels that are individually focused on upper extremity products and lower extremity products. Revenue in sports medicine and biologics decreased 3% to $11.1 million during the nine months ended September 29, 2013 from $11.4 million during the nine months ended September 30, 2012 as growth in our suture and BioFiber products was offset by decreases in certain anchor and Conexa product lines. Revenue from large joints and other decreased by 2% to $37.7 million for the nine months ended September 29, 2013 from $38.4 million for the nine months ended September 30, 2012 related primarily to declines in sales of our mature knee products as we transition to next generation products. Revenue from our large joints and other category is primarily generated in certain western European geographies which continued to experience economic pressures, negatively impacting our revenue in this category. Foreign currency exchange rate fluctuations had a positive $0.8 million impact on the large joints and other product category during the nine months ended September 29, 2013.

Revenue by geography. Revenue in the United States increased by 21% to $134.2 million for the nine months ended September 29, 2013 from $110.6 million for the nine months ended September 30, 2012, primarily due to our acquisition and integration of OrthoHelix. Excluding the impact from OrthoHelix, we believe our revenues in the United States decreased as a result of disruption in our U.S. sales channel due to our strategic initiative to establish separate sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist. While we believe this transition will increase our ability to meet our customers needs in the future, it had a negative impact on our United States revenue growth and likely will continue to negatively impact revenue growth into 2014 until the initiative is complete. International revenue increased by 6% to $93.3 million for the nine months ended September 29, 2013 from $87.8 million for the nine months ended September 30, 2012. Foreign currency exchange rate fluctuations had a positive $1.2 million impact on international revenue during the first nine months of 2013. International revenue increased due to growth in sales in France and from certain geographic expansion activities in which we increased the number of products sold through direct sales channels in countries where we historically have utilized local independent distributor representation. Our increased international revenue growth was partially offset by decreases in revenue in certain western European countries due to continued austerity measures and lower procedure volumes and a decrease in revenue in Australia due to the impact of our then pending acquisition of our lower extremity stocking distributor in that country.

Cost of goods sold. Cost of goods sold increased to $64.9 million for the nine months ended September 29, 2013 from $54.9 million for the nine months ended September 30, 2012. As a percentage of revenue, cost of goods sold increased from 28% for the first nine months of 2012 to 29% for the first nine months of 2013, primarily due to approximately $5.4 million in fair value adjustments related to inventory acquired in our acquisition of OrthoHelix and our acquisition of our stocking distributor in Canada. Excluding the inventory fair value adjustment items, our cost of goods sold as a percentage of revenue decreased due to product cost improvements, production efficiencies and the insourcing of certain products, partially offset by a higher level of excess and obsolete inventory charges and negative impacts of geographical mix. 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. In addition, the fair value adjustment charges recorded as cost of goods sold from the sell through of inventory acquired from business acquisitions should decline in future periods from the levels experienced in the fourth quarter of 2012 and the first three quarters of 2013 as all fair value adjustment charges related to the OrthoHelix acquired inventory had been recognized as of September 29, 2013.

Selling, general and administrative. Our selling, general and administrative expenses increased by 21% to $150.4 million for the nine months ended September 29, 2013 from $124.2 million for the nine months ended September 30, 2012. As a percentage of

Table of Contents

revenue, selling, general and administrative expenses were 66% and 63% for the nine months ended September 29, 2013 and the nine months ended September 30, 2012, respectively. Included in selling, general and administrative expenses for the nine months ended September 29, 2013 is $13.9 million of expense relating to OrthoHelix. Excluding this amount, the increase in total selling, general and administrative expense as a percentage of revenue was primarily a result of higher non-variable sales expenses due to the establishment of direct sales channels in the U.S, and several countries internationally and $2.3 million of expense related to the medical device excise tax in the U.S. We expect selling, general and administrative expenses as a percentage of revenue to be higher than historical levels in the near term until we experience the anticipated revenue benefits of our distribution channel transitions, integration initiatives, investments in sales resources, training and education, and new product launches, including the Aequalis Ascend Flex.

Research and development. Research and development expenses increased slightly to $16.4 million for the nine months ended September 29, 2013 from $16.3 million for the nine months ended September 30, 2012. As a percentage of revenue, research and development expenses decreased 1% to 7% for the nine months ended September 29, 2013 from 8% for the nine months ended September 30, 2012. The increase in total research and development expense of $0.1 million was primarily due to $2.0 million of research and development expense from the OrthoHelix acquisition partially offset by lower spending due to the timing of certain projects.

Amortization of intangible assets. Amortization of intangible assets increased $3.5 million to $11.6 million for the nine months ended September 29, 2013 from $8.0 million for the nine months ended September 30, 2012. The increase in amortization expense was primarily attributable to an increase in intangible assets due to our acquisition of OrthoHelix.

Special charges (income). We recorded $1.0 million in special charges for the nine months ended September 29, 2013 compared to $9.4 million for the nine months ended September 30, 2012. The $1.0 million in expense for the nine months ended September 29, 2013 is primarily comprised of $4.7 million of integration costs and distributor transition costs and $1.2 million of legal settlements in the U.S, partially offset by $4.9 million reversal of a contingent consideration liability related to the OrthoHelix acquisition due to the under-performance of legacy Tornier lower extremity products versus established revenue targets. The $9.4 million of special charges for the nine months ended September 30, 2012 was comprised of approximately $5.3 million of costs incurred in relation to our facilities consolidation initiative, $2.0 million related to bad debt expense in Italy, $0.4 million related to the departure of our former Global Chief Financial Officer, and $1.8 million of integration costs related to acquisitions. We expect to continue to record special charges during the remainder of 2013 primarily related to the ongoing integration of OrthoHelix and distribution transitions and expect these remaining amounts to range from $0.8 million to $1.8 million. Charges related to the ongoing distribution transitions may continue into 2014 until the U.S. distribution transition initiative is complete.

Interest income. Our interest income was immaterial for both the nine months ended September 29, 2013 and September 30, 2012.

Interest expense. Our interest expense increased to $5.8 million for the nine months ended September 29, 2013 from $1.4 million for the nine months ended September 30, 2012 due primarily to the establishment of our credit facility during the fourth quarter of 2012, which was used to fund our acquisition of OrthoHelix. In addition, interest expense was higher due to the accretion of interest expense related to OrthoHelix earn-out liabilities. We expect to continue to experience interest expense related to our credit agreement; however, in the second quarter of 2013, we repaid our Euro denominated term loan in full and repaid approximately $10.5 million of principal on our U.S. dollar denominated term loan, which should reduce future interest expense from levels incurred in the first half of 2013.

Loss on extinguishment of debt. We recorded $1.1 million in loss on extinguishment of debt for the nine months ended September 29, 2013 related to the write-off of a debt discount on the repayment of our Euro denominated term loan.

Foreign currency transaction loss. We recognized $1.1 million of foreign currency transaction loss for the nine months ended September 29, 2013 compared to a $0.2 million foreign currency transaction loss for the nine months ended September 30, 2012. 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 was immaterial for the nine months ended September 29, 2013 and September 30, 2012.

Income tax expense. Our effective tax rate for the nine months ended September 29, 2013 and September 30, 2012 was 5.8% and 8.4%, respectively. The change in our effective tax rate from 2012 to 2013 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

Table of Contents

losses but for which we record a valuation allowance against our deferred tax assets, and thus, cannot recognize income tax benefits. In addition, we recorded $1.0 million of income tax expense to establish a valuation allowance for deferred tax assets related to foreign stock compensation during 2013. We determined the tax planning strategies necessary to realize these deferred tax assets was no longer prudent and as a result we no longer believe these deferred tax assets are realizable. We recorded income tax expense of $1.4 million during the nine months ended September 29, 2013 compared to income tax expense of $1.3 million for the nine months ended September 30, 2012. 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 transitions to direct selling models in certain geographies and the transition of our U.S. sales channel towards focusing separately on upper and lower extremity products; 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 resulting in an accumulated deficit of $261.5 million as of September 29, 2013. Historically, our liquidity needs have been met through a combination of sales of our equity and debt securities and bank related debt. We believe that our cash and cash equivalents balance of approximately $62.6 million as of September 29, 2013, along with $30.0 million of available credit under our revolving credit facility will be sufficient to fund our working capital requirements and operations, including recent and potential distributor acquisitions to continue our U.S. channel transition and International expansion, and permit anticipated capital expenditures during the next twelve months. 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.

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

	As of	
	September 29, 2013	December 30, 2012
	($ in thousands)	
Cash and cash equivalents	$ 62,552	$ 31,108
Working capital	150,238	136,692
Available lines of credit	30,000	29,000

Total working capital was positively impacted during the first nine months of 2013 primarily as a result of the completion of our underwritten public offering in May 2013 and the subsequent repayment of certain long-term debt. The offering consisted of 8.1 million ordinary shares at a public offering price of $16.15 per ordinary share. Pursuant to the offering, we sold 5.2 million shares and certain shareholders sold 2.9 million shares, both of which were inclusive of the exercise of the underwriters over-allotment option. We received $78.9 million in net proceeds from the offering, net of the underwriters discount and commissions and offering expenses and used approximately $50.5 million of the net proceeds to pay off our $40.0 million Euro-denominated term loan and a portion of our U.S.-dollar denominated term loan. We intend to use the remaining net proceeds for working capital and general corporate purposes.

The debt that was repaid in the second quarter of 2013 related to our credit facility that was entered into in October 2012 to fund our acquisition of OrthoHelix. Under the credit facility, we have credit availability of $145 million, consisting of: (1) a senior secured term loan facility denominated in U.S. dollars in an aggregate principal amount of up to $75 million (referred to as the USD term loan facility); (2) a senior secured term loan facility denominated in Euros in an aggregate principal amount of up to the U.S. dollar equivalent of $40 million (referred to as the EUR term loan facility); and (3) a senior secured revolving credit facility denominated at our election, 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. The borrowings under the term loan facilities were used to pay a portion of the OrthoHelix acquisition consideration, and

Table of Contents

such fees, costs and expenses incurred in connection with the acquisition and the credit agreement and to repay prior existing indebtedness. The consideration paid to OrthoHelix included $100 million in cash, $38 million in equity, and potential 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. We currently have $60.7 million of debt outstanding under this credit facility.

The following summarizes the components of our consolidated statements of cash flows as of and for the nine months ended September 29, 2013 and September 30, 2012:

Operating activities. Net cash provided by operating activities was $18.3 million for the nine months ended September 29, 2013 compared to $11.1 million for the nine months ended September 30, 2012. The increase in operating cash flow was primarily attributable to an increase in cash from working capital of $4.9 million. While the net loss for the nine months ended September 29, 2013 was higher than the net loss for the nine months ended September 30, 2012, this increase was primarily due to increased non-cash expenses including depreciation and amortization of $5.4 million, charges incurred related to acquired inventory of $5.4 million, and increased obsolescence charges of $3.5 million compared to the same period of the prior year.

Investing activities. Net cash used in investing activities totaled $31.8 million during the nine months ended September 29, 2013 compared to $20.8 million during the nine months ended September 30, 2012. The increase in net cash used in investing activities was due partially to $5.7 million of cash used to acquire certain assets of our exclusive distributor in Canada, our lower extremity distributor in the United Kingdom, and the acquisition of certain distributors in the United States. In addition, our investments in instruments and investments in property, plant and equipment were higher in the first nine months of 2013 primarily driven by the launch of our Aequalis Ascend Flex shoulder project, the international launch of certain OrthoHelix products, and capitalized software development costs related to the implementation of certain new information technology systems. Expenditures related to property, plant and equipment were $7.5 million and $7.9 million for the nine months ended September 29, 2013 and September 30, 2012, respectively. Expenditures related to instruments were $16.6 million and $9.2 million for the nine months ended September 29, 2013 and September 30, 2012, respectively.

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 increased to $44.1 million during the nine months ended September 29, 2013, from $13.4 million during the nine months ended September 30, 2012. This increase was primarily related to $78.9 million in net proceeds from our underwritten public offering completed in May 2013, partially offset by the repayment of long-term debt, which included the payoff of the senior secured term loan facility denominated in Euros (approximately 30.7 million) and $10.5 million of our senior secured term loan facility denominated in U.S. dollars.

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.

23

Table of Contents

Contractual Obligations and Commitments

We refer you to the description of our contractual obligations and commitments as of December 30, 2012 as set forth in our annual report on Form 10-K for the fiscal year ended December 30, 2012. There were no material changes to such information since that date through September 29, 2013, except for the following: approximately $2.1 million of potential future earn-out obligations, all due in the next one to two years, incurred in connection with our acquisition of certain assets of our exclusive distributor in Canada, our acquisition of certain assets of our lower extremities distributor in the United Kingdom and our acquisition of certain distributors in the United States; a $4.9 million gain recognized on the reversal of a contingent liability, payable in one to two years, related to our acquisition of OrthoHelix; and the repayment of approximately $50.5 million of our senior secured term debt. We are updating the following lines from the table in our Form 10-K to reflect the changes in senior secured term debt:

		Payment Due By Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1 -3 Years**	**3 - 5 Years**	**More than 5 Years**
		($ in thousands)			
Amounts reflected in consolidated balance sheet:					
Bank debt	$ 63,950	$ 703	$ 1,526	$ 61,721	$
Amounts not reflected in consolidated balance sheet:					
Interest on bank debt	11,999	2,769	5,428	3,802	

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 December 30, 2012. Certain of our 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 December 30, 2012. There have been no significant changes to the policies related to our critical accounting estimates since December 30, 2012.

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 revolving credit facility and U.S. dollar denominated term loan bear interest at variable rates. As of September 29, 2013, we had no borrowings under our revolving credit facility and $67.3 million in borrowings under our U.S. dollar denominated term loan and other debt. Based upon this debt level, and the LIBOR floor on our interest rate, a 100 basis point increase in the annual interest rate on such borrowings would have an immaterial impact on our interest expense on an annual basis.

At our option, borrowings under our revolving credit facility and our U.S. dollar denominated term loan 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 rate in effect on such day plus 1/2 of 1%, and (iii) the adjusted LIBO rate 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 credit agreement), or (b) in 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 credit agreement) if such loan is made in a currency other than U.S. dollars or from a lending office in the United Kingdom or a participating member state (as defined in our credit agreement).

At September 29, 2013, our cash and cash equivalents were $62.6 million. Based on our annualized average interest rate, a 100 basis point decrease in the annual interest rate on such balances would not result in a material impact on our interest income on an annual basis.

Table of Contents

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 the nine months ended September 29, 2013 and September 30, 2012, approximately 41% and 44%, respectively, of our revenues were denominated in foreign currencies, respectively. 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, to some extent. 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.

In the nine months ended September 29, 2013, approximately 76% of our revenues denominated in foreign currencies were derived from European Union 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 re-measurement 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 2012 and the first nine months of 2013, we economically hedged our exposure to fluctuations in the Euro and other currencies by entering into foreign exchange forward contracts.

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 amended) as of September 29, 2013. 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 Tornier required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, 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 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except that we are currently in the process of evaluating and integrating OrthoHelix s internal controls into ours.

25

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Not applicable.

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 29, 2013, we had an accumulated deficit of $261.5 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, development, commercialization and market acceptance of new products, the results and scope of ongoing research and development projects, the success of our direct sales force and independent distributor and sales agency organization and transitions related thereto, competing technologies and market developments and regulatory requirements and delays. As a result, we may continue to incur operating losses for the foreseeable future. These losses will continue to have an adverse impact on our shareholders equity, and we may never achieve or sustain profitability.

We rely on our distributors, independent sales agencies and their representatives to market and sell our products in certain territories. A failure to maintain our existing relationships with or changes and transitions with respect to our distributors, independent sales agencies and their representatives have had and could continue to have an adverse effect on our operations and operating results.

Our success depends largely upon our ability to motivate our distributors, independent sales agencies and their representatives to sell our products in certain territories. We depend on their sales and service expertise and their relationships with surgeons in the marketplace. In the United States, we historically have had a single sales channel that consisted of a network of independent commission-based sales agencies, along with direct sales representation in certain territories. Since our acquisition of OrthoHelix in October 2012, we have been in the process of executing our integration strategy to establish separate U.S. sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist as we believe that this increased focus will allow us to increase the product proficiency of our sales representatives and increase our selling opportunities by improving our overall procedure coverage, leveraging our entire product portfolio, and accessing new specialists and accounts. Internationally, we currently utilize several distribution approaches depending on individual market requirements and, as a result, our international distribution system consists of 13 direct sales offices and approximately 25 distributors that sell our products in approximately 40 countries. As part of our strategy to grow internationally, we have selectively converted from distributor representation to direct sales representation in certain countries, including the United Kingdom, Denmark, Belgium, Luxembourg, Japan, Australia and Canada, and we have selectively converted from direct sales representation to distributor representation in certain countries, including Spain, during the past few years.

We do not control our distributors or independent sales agencies and they may not be successful in implementing our marketing plans. Some of our distributors and sales agencies do not sell our products exclusively and may offer similar products from other orthopaedic companies. Our distributors and independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products or may focus their sales efforts on other products that produce greater commissions for them. A failure to maintain our existing relationships with or changes and transitions with respect to our distributors and independent sales agencies and their representatives have had and could continue to have an adverse effect on our operations and operating results. As part of our OrthoHelix integration initiative to establish separate U.S. sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist and as part of our strategic initiative to increase the overall productivity of our sales organization, we have terminated some of our existing sales relationships with certain distributors and independent sales agencies. Upon these terminations, we have entered into agreements with existing distributors and sales agencies to take on the impacted products or territories, contracted with new distributors and sales agencies, hired direct sales representatives, or used a combination of these options. These terminations, changes and transitions have resulted in, and may continue to result in, disruption in our sales channels, including in particular in the United States where several transitions have occurred during the past year or so, thereby adversely affecting our operations and operating results. It is also possible that we may become subject to litigation and incur future charges and cash expenditures in connection with these changes and transitions, which charges and cash expenditures would adversely affect our operating results.

Table of Contents

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 new products and technologies also could render our existing products obsolete and thus adversely affect sales of our existing products. 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. 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 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. During the third quarter of 2013, we believe our revenues were adversely affected by increased competition, especially in light of the transitions in our U.S. sales channel. We face competition from large diversified orthopaedic manufacturers, such as DePuy Orthopaedics, Inc., a Johnson & Johnson subsidiary, Zimmer Corporation, Biomet, Inc. 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 over us, including:

- greater financial and human resources for product development and sales and marketing;
- greater name recognition;
- established relationships with surgeons, hospitals and third-party payors;
- broader product lines and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage;

established sales and marketing and distribution networks; and

more experience in conducting research and development, manufacturing, preparing regulatory submissions and obtaining regulatory clearances or approvals for products.

We also compete against smaller, entrepreneurial companies with niche product lines. Some of our competitors have indicated recently an increased focus on the extremities market, which is our primary strategic focus. Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearances or approvals for competing products more rapidly than us, develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive or acquire technologies and technology licenses complementary to our products or advantageous to our business. We also compete with other organizations in recruiting and retaining qualified scientific and management personnel. 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 markets outside the United States that are subject to political, economic and social instability.

We derive a significant portion of our revenue from operations in markets outside the United States. Our distribution system outside United States consists of 13 direct sales offices and approximately 25 distribution partners, who together sell in approximately 40 countries. Most of these countries are, to some degree, subject to political, economic and social instability. For the nine months ended September 29, 2013 and the year ended December 30, 2012, approximately 41% and 44% of our revenue, respectively, was derived from our operations outside the United States, including 18% and 19% of our revenue from France, respectively. In the future,

Table of Contents

we intend to further expand our international operations into key markets, such as Brazil and China, as we have done, for example, in 2013, when we acquired certain assets of our distributors in Australia, Canada and the United Kingdom and established direct sales forces in such countries, and in 2012, when we opened a direct sales office in Japan and acquired our exclusive distributor in Belgium and Luxembourg. 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 and import 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.

Not only are we subject to the laws of jurisdictions located outside the United States in which we do business, but 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. We also are dependent upon the compliance of our distributors with foreign laws and the U.S. Foreign Corrupt Practices Act, or the FCPA, as it relates to certain facilitating payments made to those employed by or acting on behalf of a foreign government in the procurement, sale and prescription of medical devices. If a distributor were to go out of

Table of Contents

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 international 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.

A substantial portion of our revenue outside the United States is generated in Europe, including in particular France. 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 continued 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 continue to 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.

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 that weakness in the global economy 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.

Table of Contents

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 also believe that if patient outcomes are improved as a result of extremity procedures over alternative treatments or no treatment, more patients will select to undergo extremity procedures as opposed to alternative treatments or no treatment and the market for our extremities 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 29, 2013 and the year ended December 30, 2012, our upper extremity joints and trauma products generated approximately 60% and 63% of our revenue, respectively. We expect the shoulder to continue to be the largest and most important product category for us for the foreseeable future. In particular, we anticipate that our upper extremity joints and trauma product revenue will be favorably impacted in future periods as a result of the recent launch of our Aequalis Ascend Flex. However, our expectations may prove to be incorrect and it is possible that the market acceptance of the Aequalis Ascend Flex will not meet our expectations or may have the effect of negatively impacting sales of our other shoulder products. A decline in our upper extremity joints and trauma product revenue as a result of lack of market acceptance of new products, the effect of new products on sales of existing products, 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 that we believe will 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.

Table of Contents

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 continue to bring in-house the manufacturing of certain of our products that are currently manufactured by third parties. Should we encounter difficulties in manufacturing these or other products, it could adversely affect our business.

We intend to continue our initiative to bring in-house the manufacturing of certain of our products, 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. In addition, other products that we choose to bring in-house could encounter similar difficulties. Manufacturing and product quality issues may also 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 our 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.

Our facilities consolidation initiative completed in 2012 may not result in anticipated operational efficiencies, expense savings and other benefits and could have an unintended adverse impact on our business.

During 2012, we implemented a facilities consolidation initiative pursuant to which we consolidated a number of our facilities in France, Ireland and the United States. The facilities consolidation initiative was 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 and our St. Ismier, France manufacturing facility into our existing Montbonnot, France manufacturing facility. We also leased a new facility located in Bloomington, Minnesota to use as our U.S. business headquarters and consolidated our Minneapolis-based marketing, training, regulatory, clinical, supply chain and corporate functions with our Stafford, Texas-based distribution operations. In connection with the facilities consolidation, we recorded 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 during 2012, aggregating in $6.4 million of expense for 2012. Since the facilities consolidation is complete, we did not record any significant additional expense related to the facilities consolidation during the nine months ended September 29, 2013 and do not expect to record any significant additional expense related to the facilities consolidation during the remainder of 2013. Although we believe that the facilities consolidation has resulted and will continue to result in anticipated operational efficiencies, expense savings and other benefits, we may be incorrect. If the facilities consolidation results in unanticipated expenses and charges, including litigation expenses, and has unintended impacts on our business, including in particular our new product development efforts, or if does not produce the operational efficiencies, expense savings and other benefits that we anticipated, we may disappoint investors and shareholders and it is possible that further restructuring activities might become necessary, resulting in additional future charges. In addition, the facilities consolidation could result in deficiencies in

our internal control over financial reporting and other controls and procedures.

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. operating subsidiaries, Tornier, Inc. and OrthoHelix Surgical Designs, Inc., are currently subject to the U.S. Foreign Corrupt Practices Act. 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

Table of Contents

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. During the past few years, the SEC has increased its enforcement of violations of the FCPA against companies, including several medical device companies. Although we do not believe we are currently a target, any investigation of any potential violations of the FCPA or other anticorruption laws by U.S. or foreign authorities also could have an adverse impact on our business, financial condition and operating results.

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

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

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

Table of Contents

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.

We may not achieve our financial guidance or projected goals and objectives in the time periods that we anticipate or announce publicly, which could have an adverse effect on our business and could cause the market price of our ordinary shares to decline.

On a quarterly basis, we typically provide projected financial information, such as our anticipated quarterly and annual revenues, adjusted earnings before interest, taxes and depreciation and net loss. These financial projections are based on management s then current expectations and typically do not contain any significant margin of error or cushion for any specific uncertainties or for the uncertainties inherent in all financial forecasting. The failure to achieve our financial projections or the projections of analysts and investors could have an adverse effect on our business, disappoint analysts and investors and cause the market price of our ordinary shares to decline. Since our initial public offering, our revenue performance has been outside of our guidance range in certain quarters, including the third quarter of 2013, which has negatively impacted the market price of our ordinary shares and could do so in the future should our results fall outside of our guidance range and the expectations of analysts and investors.

We also set goals and objectives for, and make public statements regarding, the timing of certain accomplishments and milestones regarding our business, such as the timing of new products, regulatory actions and anticipated distributor and sales representative transitions. The actual timing of these events can vary dramatically due to a number of factors including the risk factors described in this report. As a result, there can be no assurance that we will succeed in achieving our projected goals and objectives in the time periods that we anticipate or announce publicly. The failure to achieve such projected goals and objectives in the time periods that we anticipate or announce publicly could have an adverse effect on our business, disappoint investors and analysts and cause the market price of our ordinary shares to decline.

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 and other costs;

Table of Contents

substantial monetary awards to or costly settlements with patients;

product recalls;

loss of revenue; and

the inability to commercialize new products or product candidates.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business and operating results could suffer. 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. In addition, a recall of our products, whether or not as a result of a product liability claim, could result in decreased demand for our products, injury to our reputation, significant litigation and other costs, substantial monetary awards to or costly settlements with patients, loss of revenue and our inability to commercialize new products or product candidates.

Our inability to maintain adequate working relationships with external research and development consultants and surgeons could have a negative impact on our ability to develop 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 U.S. federal and state and international 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 our 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 balance was $84.6 million and $86.7 million at September 29, 2013 and December 30, 2012, respectively, and our total consolidated instrument balance was $58.7 million and $51.4 million at September 29, 2013 and December 30, 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 acquisition of OrthoHelix in October 2012 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 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. During 2013, we acquired certain assets of our distributors in Australia, Canada and the United Kingdom and established direct sales forces in such countries, and during 2012, we acquired our exclusive distributor in Belgium and Luxembourg and established direct sales forces in such countries. In addition, we may pursue additional acquisitions of other distributors, 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 these recent acquisitions and any future acquisitions, we may experience:

- difficulties in integrating the acquired businesses and their respective personnel and products into our existing business;

- difficulties in integrating commercial organizations, including in particular distribution and sales representative arrangements;

- difficulties or delays in realizing the anticipated benefits of our recent acquisitions or any additional acquired companies and their products;

Table of Contents

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;

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;

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

any unforeseen compliance risks and accompanying financial and reputational exposure or loss not uncovered in the due diligence process and which are imputed to Tornier, such as compliance with federal laws and regulations, the advertising and promotion regulations under the federal

Food, Drug and Cosmetic Act, the Anti-kickback Statute, the False Claims Act, the Physician Sunshine Payments Act and other applicable state laws.

In addition, we may have to incur debt or issue equity securities to pay for an 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 under two senior secured term loans, the proceeds of which 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 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;

Table of Contents

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

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

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

As a result of these risks, the OrthoHelix acquisition may not contribute to our earnings as expected, we may not achieve expected revenue synergies or our return on invested capital targets when expected, or at all, and we may not achieve the other anticipated strategic and financial benefits of the transaction. For example, some of these risks materialized during the nine months ended September 29, 2013. As part of our OrthoHelix integration initiative to establish separate U.S. sales channels that are individually focused on the upper extremity specialist and the lower extremity specialist, we terminated some of our existing sales relationships with certain distributors and independent sales agencies. Upon these terminations, we entered into agreements with existing distributors and sales agencies to take on the impacted products or territories, contracted with new distributors and sales agencies, hired direct sales representatives, or used a combination of these options. These terminations, changes and transitions have resulted and may continue to result in disruption in our U.S. sales channel, thereby adversely affecting our operations and operating results.

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 future success depends, in large part, upon our ability to retain and motivate our management team and key managerial, scientific, sales and technical personnel. Key personnel may depart because of difficulties with change or a desire not to remain with our company. Any unanticipated loss or interruption of services of our management team and our key personnel could significantly reduce our ability to meet our strategic objectives because it may not be possible for us to find appropriate replacement personnel should the need arise. 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 facility in Bloomington, Minnesota, and a warehouse in Montbonnot, France, both of which 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.

Table of Contents

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:

- continue our research and development;
- develop, obtain required regulatory approvals or clearances and commercialize new products;
- make changes in our distribution channels;
- defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights and enforce our patent and other intellectual property rights; and
- acquire companies and in-license products or intellectual property.

We believe that our cash and cash equivalents balance of $62.6 million as of September 29, 2013, anticipated cash receipts generated from revenue of our products and available credit under our $30.0 million senior secured revolving credit facility, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, our future funding requirements will depend on many factors, including:

- required regulatory approval, commercial introduction and 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 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 our product offering inventories;

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;

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.

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.

Any lack of borrowing availability under our 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 $30.0 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 the 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.

Table of Contents

Both the $30.0 million revolving credit facility and the aggregate $60.7 million of term loans under our credit agreement as of September 29, 2013 are secured by all of our assets (subject to certain exceptions) and except to the extent otherwise permitted under the terms of our 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. Any lack of 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.

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. As of September 29, 2013, we had senior secured term loans outstanding in the aggregate principal amount of $60.7 million. In addition, as of September 29, 2013, we have $30.0 million of credit availability under our senior secured 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 utilize our existing available credit under our senior secured revolving line of credit or 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 credit agreement contains restrictive covenants that may limit our operating flexibility.

The agreement relating to our senior secured term loans and senior secured revolving credit facility contains 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 $20.0 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 operating results.

In connection with our acquisition of OrthoHelix, we agreed to made additional earn-out payments of up to an aggregate of $20.0 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, operating results and financial condition may be adversely affected.

Table of Contents

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

We operate through multiple entities and in multiple income tax jurisdictions with different income tax rates both inside and outside the United States 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 $247.7 million in goodwill and $119.7 million in other acquired intangible assets, together representing 53% of our total assets as of September 29, 2013. The determination of related estimated useful lives and whether these assets are impaired involves significant judgments. Our ability to accurately predict future cash flows related to these intangible assets may be adversely affected by unforeseen and uncontrollable events. In the highly competitive medical device industry, new technologies could impair the value of our intangible assets if they create market conditions that adversely affect the competitiveness of our products. We test our goodwill for impairment in the fourth quarter of each year, but we also test goodwill and other intangible assets for impairment at any time when there is a change in circumstances that indicates that the carrying value of these assets may be impaired. Any future determination that these assets are carried at greater than their fair value could result in substantial non-cash impairment charges, which could significantly impact our reported operating results.

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. As part of the Budget Control Act passed in August 2011 to extend the federal debt limit and reduce government spending, $1.2 trillion in automatic spending cuts (known as sequestration) over the next decade. Half of the automatic reductions would come from lowering the caps imposed on non-defense discretionary spending and cutting domestic entitlement programs, including aggregate reductions in payments to Medicare providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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. Changes in reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our products may cause our revenue to decline.

Table of Contents

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 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;
- premarket clearance and approval;
- marketing, sales and distribution (including making product claims);
- advertising and promotion;

Table of Contents

product modifications;

recordkeeping procedures;

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, a *de novo* approval or a 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. To establish substantial equivalence which allows the device to be marketed, the applicant must demonstrate the device has the: (i) the same intended use; (ii) the same technological characteristics; and (iii) to the extent the technological characteristic are different, that they do not raise different questions of safety and effectiveness. Clinical data is sometimes required to support substantial equivalence, but FDA s expectations for data are often unclear and do change. Another procedure for obtaining marketing authorization for a medical device is the *de novo* classification procedure, pursuant to which FDA may authorize the marketing of a moderate to low risk device that has no predicate. These submissions typically require more information (i.e. non-clinical and/or clinical performance data) and take longer than a 510(k), but require less data and a shorter time period than a PMA approval. If the FDA grants the *de novo* request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted, and the device becomes a 510(k) predicate for future devices seeking to call it a predicate. 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) or a PMA. Both the 510(k) and PMA processes can be expensive, lengthy and sometimes unpredictable. The processes also entail significant user fees, unless exempt. The FDA s 510(k) clearance process usually takes from six to 18 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 and have not gone through the *de novo* classification for marketing clearance, 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 510(k) clearances

with respect to future products.

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

- we may not be able to demonstrate to the FDA s satisfaction that our products meet the definition of substantial equivalence or meet the standard for the FDA to grant a petition for de novo classification;
- we may not be able to demonstrate to the FDA s satisfaction that our products are safe and effective for their intended uses;
- 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 (notice of violation) letters or public warning letters to us;

Table of Contents

imposing fines and penalties on us;

obtaining an injunction or administrative detention preventing us from manufacturing or selling our products;

seizing products to prevent sale or transport or export;

bringing civil or criminal charges against us;

recalling our products;

detaining our products at U.S. Customs;

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; 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 product in countries outside the United States, 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. In addition, some countries outside of the United States, such as France, have adopted physician payment laws similar to the Physician Sunshine Payment Act in the United States.

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 (and often does) review the manufacturer s decision. The FDA may not agree with a manufacturer s decision regarding whether a new clearance or approval is necessary for a modification, and may retroactively require the manufacturer to submit a premarket notification requesting 510(k) clearance or an application for PMA. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. No assurance can be given that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA. The issue of whether a product modification is significant enough to require a 510(k), as opposed to a simple letter-to-file documenting the change, is in a state of flux. In 1997, FDA issued a guidance to address this issue and it is a guidance with which FDA and industry is very familiar. In 2011, FDA proposed a new modifications guidance that was very controversial with industry because industry interpreted the guidance to reflect FDA s view that it would require more 510(k)s than under the 1997 modifications guidance. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, FDASIA, was signed into law. Among other things, FDASIA obligates the FDA to prepare a report for Congress on the FDA s approach for

Table of Contents

determining when a new 510(k) will be required for modifications or changes to a previously cleared device. After submitting this report, the FDA is expected to issue revised guidance to assist device manufacturers in making this determination. Until then, manufacturers may continue to adhere to the FDA s 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA s continuing scrutiny of these issues remains unclear.

If the FDA requires us to cease marketing and recall a 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 (referred to as the Physician Sunshine Payment Act), which reporting requirements will be difficult to define, track and report. Manufacturers were required to begin data collection on August 1, 2013 and must report such data to CMS by March 31, 2014 and by the 90th day of each calendar year thereafter;
- 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

Table of Contents

cash flows. The tax could create a risk up to 2.3% of our United States revenue. In the nine months ended September 29, 2013, we recognized $2.3 million of expense within selling, general and administrative expenses on the consolidated statement of operations related to the medical device excise tax.

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, reimbursement advice or training of sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training or promotional or reimbursement materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, a 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 August 2013, we initiated a voluntary Class II recall for instrumentation contained within the Aequalis Reversed II and the Aequalis Reversed Fracture instrument sets. We notified our distributors, sales representatives and all direct consignees and directed them to return the affected instrumentation to us in exchange for redesigned instruments. As another example, in 2011, we recalled a small number of medical devices due to risks associated with loosening of humeral screws. We properly disposed of the recalled articles thereafter and the FDA considered the recall terminated in July 2012. 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

Table of Contents

Authority Reports, or NCARs. The Medical Device Vigilance System is further intended to facilitate a direct, early and harmonized implementation of Field Safety Corrective Actions, or FSCAs across the Member States of the EEA where the device is in use. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

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

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

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

We and certain of our third-party manufacturers are required to comply with the FDA s current Good Manufacturing (cGMP) and Quality System Regulations, 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. In January 2013, our OrthoHelix facility located in Medina, Ohio was subject to a routine FDA inspection. The inspection resulted in the issuance of a Form FDA-483 listing four inspectional observations. The FDA s observations related to our documentation of corrective and preventative actions, procedures for receiving, reviewing and evaluating complaints, procedures to control product that does not conform to specified requirements and procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. Although we believe we have corrected all four of these observations, the FDA could disagree with our conclusion and corrective and remedial measures. In April 2013, our manufacturing facility located in Montbonnot, France was subject to a routine FDA inspection. The inspection resulted in the issuance of a Form FDA-483 listing one inspectional observation. The FDA s observation related to our establishment of records of acceptable suppliers, contractors and consultants. Although we believe we have corrected all five of these observations, the FDA could disagree with our conclusion and corrective and remedial measures. 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, disgorgement of profits, criminal 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 approval 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.

Table of Contents

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. Many of these standards simply create industry standards of conduct, other standards tie into compliance with the advertising and promotion regulations under the Food, Drug & Cosmetic Act, the Anti-kickback Statute, the False Claims Act, HIPAA and the Physician Sunshine Payment Act. We use many distributors and independent sales representatives in certain territories and thus rely upon their compliance with applicable laws and regulations, such as with the advertising and promotion regulations under the federal Food, Drug and Cosmetic Act, the Anti-kickback Statute, the False Claims Act, the Physician Sunshine Payments Act, the French Sunshine Act, and other applicable federal, state or international laws. The failure by us or one of our distributors, representatives or suppliers to comply with applicable legal and 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, seizing, detaining or enjoining the sale of our products;
- withdrawing, delaying or denying approvals or clearances for our products;
- issuing warning letters or untitled letters;
- imposing operating restrictions;
- imposing injunctions; and
- commencing criminal prosecutions.

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

revenue to suffer and may prevent us from generating revenue.

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

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

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

Table of Contents

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, state, and international healthcare laws, including fraud and abuse, false claims 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, bundling and rebate policies, grants for physician-initiated trials and CME, and other remunerative 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 (such as the federal False Claims Act) 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, this impacts and regulates the reimbursement advice we give to our customers as it cannot be inaccurate and must relate to on-label uses of our products;

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

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

preempted by HIPAA, thus complicating compliance efforts.

If our past or present operations, or those of our independent sales agencies, are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal healthcare programs and the curtailment or restructuring of our operations. Similarly, if the healthcare providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our 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 (known as the Physician Sunshine Payment Act). 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

Table of Contents

(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. Manufacturers were required to begin data collection on August 1, 2013 and will be required to report such data to CMS by March 31, 2014 and by the 90th day of each calendar year thereafter.

In addition, there has been a recent trend of increased state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. Some countries, such as France, also regulate payments made to physicians. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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 for a combined fine of $311.0 million. The companies agreed to new corporate compliance procedures and federal monitoring. At issue were alleged 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.

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.

Table of Contents

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 (510(k)) or approval (PMA).

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: (i) minimally manipulated; (ii) intended for homologous use as determined by labeling, advertising or other indications of the manufacturer s objective intent for a homologous use; (iii) 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 (iv) 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.

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

Table of Contents

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, Authorization 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. 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 Financial Accounting Standards Board. These rules and regulations continue to evolve in scope and complexity and many new requirements have been created in response to laws enacted by Congress, making compliance more difficult and uncertain. For example, our efforts to comply with the Dodd-Frank Wall Street Reform and Consumer Protection Act and other new regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related to Our Intellectual Property

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

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

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

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

Table of Contents

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. transitioned 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 have recently become effective. 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 relate to the design and manufacturing of some of our products. The loss of such licenses could prevent us from manufacturing, marketing and selling these products, which could harm our business.

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

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

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

thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

In any infringement lawsuit, a third party could seek to enjoin, or prevent, us from commercializing our existing or future products, or may seek damages from us, and any such lawsuit would likely be expensive for us to defend against. If we lose one of these proceedings, a court or a similar foreign governing body could require us to pay significant damages to third parties, seek licenses from third parties, pay ongoing royalties, redesign our products so that they do not infringe or prevent us from manufacturing, using or selling our products. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

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

Table of Contents

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 $14.53 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, and in particular variations that deviate from our projected financial information;
- announcements of new investments, acquisitions, strategic partnerships or joint ventures;
- announcements of new products by us or our competitors;
- announcements of divestitures or discontinuance of products or assets;
- 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.

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 entities affiliated with our directors, including TMG Holdings Coöperatief U.A., or TMG, Vertical Fund I, L.P., Vertical Fund II, L.P. and KCH Oslo AS, which requires us to register ordinary shares held by these persons under the Securities Act, subject to certain limitations, restrictions and conditions.

Table of Contents

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 directors or executive officers 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 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. Certain of our directors and executive officers and many 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 us or them 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 articles of association, we indemnify and hold our directors harmless against all claims and suits brought against them, subject to limited exceptions. There is doubt, however, as to whether U.S. courts would enforce such an indemnity provision in an action brought against one of our directors in the United States under U.S. securities laws.

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 articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. For example, Dutch law does not provide for a shareholder derivative action.

We do not anticipate paying dividends on our ordinary shares.

Our articles of association prescribe that profits or reserves appearing from our annual accounts adopted by the general meeting shall be at the disposal of the general meeting. We will have power to make distributions to shareholders and other persons entitled to distributable profits only to the extent that our equity exceeds the sum of the paid and called-up portion of the ordinary share capital and the reserves that must be maintained in accordance with provisions of Dutch law or our articles of association. The profits must first be used to set up and maintain reserves required by law and must then be set off against certain financial losses. We may not make any distribution of profits on ordinary shares that we hold. The general meeting, whether or not upon the proposal of our board of directors, determines whether and how much of the remaining profit they will reserve and the manner and date of such distribution. All calculations to determine the amounts available for dividends will be based on our annual accounts, which may be different from our consolidated financial statements, such as those incorporated by reference into this prospectus. Our statutory accounts to date have been prepared and will continue to be prepared under Dutch generally accepted accounting principles and are deposited with the Trade Register in Amsterdam, The Netherlands. 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. In addition, our credit agreement contains covenants limiting our ability to pay cash dividends.

Warburg Pincus (Bermuda) Private Equity IX, L.P. and its affiliates control approximately 33.2% 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 33.2% 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 Holdings Coöperatief U.A., or TMG, an affiliate of Warburg Pincus, the right to designate three directors to be nominated to our board of directors for so long as TMG beneficially owns at least 25% of our outstanding ordinary shares, two directors for so long as TMG beneficially owns at least 10% but less than 25% of our outstanding ordinary shares and one director for so long as TMG beneficially owns at least 5% but less than 10% of our outstanding ordinary shares, and we have agreed to use our reasonable best efforts to cause the TMG designees to be elected.

Table of Contents

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 any deficiencies in our internal controls.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. A material weakness, as defined in the standards established by the Public Company Accounting Oversight Board, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for 2009, we identified a material weakness in our internal control over financial reporting relating to our audited financial statements for 2007 and 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Recent Sales of Unregistered Securities

During the third quarter of 2013, 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.

Issuer Purchases of Equity Securities

We did not purchase any ordinary shares or other equity securities of ours during the third quarter of 2013.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

Table of Contents

ITEM 6. EXHIBITS.

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

Exhibit No.	Description
12.1	Ratio of Earnings to Fixed Charges (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)
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 29, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets as of September 29, 2013 and September 30, 2012, (ii) the unaudited Consolidated Statements of Operations for the three and nine months ended September 29, 2013 and September 30, 2012, (iii) the unaudited Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 29, 2013 and September 30, 2012, (iv) the unaudited Consolidated Statements of Cash Flows for the nine months ended September 29, 2013 and September 30, 2012, and (v) Notes to Consolidated Financial Statements (Filed herewith)

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 6, 2013

By: /s/ David H. Mowry
David H. Mowry
President and Chief Executive Officer
(principal executive officer)

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

Table of Contents

TORNIER N.V.

QUARTERLY REPORT ON FORM 10-Q

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
12.1	Ratio of Earnings to Fixed Charges	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
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 29, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets as of September 29, 2013 and September 30, 2012, (ii) the unaudited Consolidated Statements of Operations for the three and nine months ended September 29, 2013 and September 30, 2012, (iii) the unaudited Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 29, 2013 and September 30, 2012, (iv) the unaudited Consolidated Statements of Cash Flows for the nine months ended September 29, 2013 and September 30, 2012, and (v) Notes to Consolidated Financial Statements	Filed herewith