ORTHOFIX INTERNATIONAL N V
Form 10-Q
August 01, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 June 30, 2016

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: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao	Not applicable
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7 Abraham de Veerstraat	
Curaçao	Not applicable
(Address of principal executive offices)	(Zip Code)

599-9-4658525

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

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

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 July 29, 2016, 18,124,817 shares of common stock were issued and outstanding.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,” “potential,” or “continue” or other comparable termino These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, or the risk factors described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, to reflect new information, the occurrence of future events or circumstances or otherwise.

Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: the expected sales of our products, including recently launched products; the continuation of our ongoing share repurchase program; our ongoing settlement discussions with the Division of Enforcement of the Securities Exchange Commission (the “SEC”) related to investigation that arose out of our prior accounting review and restatements of financial statements and our review of allegations of improper payments involving our Brazil-based subsidiary (which review is described in Part I, Item 3, “Legal Proceedings”); the geographic concentration of certain accounts receivable in countries or territories that are facing severe fiscal challenges; unanticipated expenditures; changing relationships with customers, suppliers, strategic partners and lenders; changes to and the interpretation of governmental regulations; the resolution of pending litigation matters (including our indemnification obligations with respect to certain product liability claims against our former sports medicine global business unit (as further described in Part I, Item 3, “Legal Proceedings”); our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (and related terms of probation); risks relating to the protection of intellectual property; changes to the reimbursement policies of third parties; the impact of competitive products; changes to the competitive environment; the acceptance of new products in the market; conditions of the orthopedic and spine industries; credit markets and the global economy; corporate development and market development activities, including acquisitions or divestitures; unexpected costs or operating unit performance related to recent acquisitions; and other risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as well as in other current and periodic reports that we file with the SEC in the future.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Balance Sheets

(U.S. Dollars, in thousands, except share data)	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 40,482	$ 63,663
Trade accounts receivable, less allowance for doubtful accounts of $9,560 and $8,923 at June 30, 2016 and December 31, 2015, respectively	56,438	59,839
Inventories	61,334	57,563
Prepaid expenses and other current assets	19,734	31,187
Total current assets	177,988	212,252
Property, plant and equipment, net	52,499	52,306
Patents and other intangible assets, net	7,822	5,302
Goodwill	53,565	53,565
Deferred income taxes	56,443	57,306
Other long-term assets	16,421	19,491
Total assets	$ 364,738	$ 400,222
Liabilities and shareholders' equity		
Current liabilities:		
Trade accounts payable	$ 13,676	$ 16,391
Other current liabilities	63,523	65,597
Total current liabilities	77,199	81,988
Other long-term liabilities	29,308	27,923
Total liabilities	106,507	109,911
Contingencies (Note 11)		
Shareholders' equity:		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,108,540 and 18,659,696 issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	1,811	1,866
Additional paid-in capital	205,337	232,126
Retained earnings	59,057	62,551
Accumulated other comprehensive loss	(7,974)	(6,232)
Total shareholders' equity	258,231	290,311
Total liabilities and shareholders' equity	$ 364,738	$ 400,222

The accompanying notes form an integral part of these condensed consolidated financial statements

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30, 2016	2015	Six Months Ended June 30, 2016	2015
Product sales	$90,868	$86,868	$176,493	$163,700
Marketing service fees	13,207	14,086	26,261	27,016
Net sales	104,075	100,954	202,754	190,716
Cost of sales	22,515	21,910	44,651	41,249
Gross profit	81,560	79,044	158,103	149,467
Operating expenses				
Sales and marketing	46,037	42,946	90,853	87,231
General and administrative	17,954	22,506	34,672	44,075
Research and development	6,792	6,451	14,428	12,296
Restatements and related costs	545	2,213	790	8,129
Charges related to U.S. Government resolutions (Note 11)	12,870	—	12,870	—
	84,198	74,116	153,613	151,731
Operating (loss) income	(2,638)	4,928	4,490	(2,264)
Other income and expense				
Interest (expense) income, net	(113)	74	(151)	(198)
Other income, net	147	853	1,980	1,544
	34	927	1,829	1,346
(Loss) income before income taxes	(2,604)	5,855	6,319	(918)
Income tax expense	(3,685)	(1,778)	(7,979)	(2,742)
Net (loss) income from continuing operations	(6,289)	4,077	(1,660)	(3,660)
Discontinued operations (Note 11)				
Loss from discontinued operations	(1,572)	(730)	(2,562)	(1,511)
Income tax benefit	474	225	728	364
Net loss from discontinued operations	(1,098)	(505)	(1,834)	(1,147)
Net (loss) income	$(7,387)	$3,572	$(3,494)	$(4,807)
Net income (loss) per common share—basic:				
Net (loss) income from continuing operations	$(0.35)	$0.22	$(0.09)	$(0.20)
Net loss from discontinued operations	(0.06)	(0.03)	(0.10)	(0.06)
Net (loss) income per common share—basic	$(0.41)	$0.19	$(0.19)	$(0.26)
Net income (loss) per common share—diluted:				
Net (loss) income from continuing operations	$(0.35)	$0.21	$(0.09)	$(0.20)
Net loss from discontinued operations	(0.06)	(0.02)	(0.10)	(0.06)
Net (loss) income per common share—diluted	$(0.41)	$0.19	$(0.19)	$(0.26)
Weighted average number of common shares:				
Basic	18,147,681	18,769,415	18,312,781	18,750,804
Diluted	18,147,681	18,989,579	18,312,781	18,750,804
Other comprehensive income (loss):				
Unrealized gain on derivative instruments, net of tax	50	271	76	936

Unrealized loss on debt securities, net of tax	(1,942)	—	(2,469)	—
Foreign currency translation adjustment	(570)	1,559	651	(3,301)
Comprehensive (loss) income	$(9,849)	$5,402	$(5,236)	$(7,172)

The accompanying notes form an integral part of these condensed consolidated financial statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

(Unaudited, U.S. Dollars, in thousands)	Six Months Ended June 30, 2016	2015
Cash flows from operating activities:		
Net cash provided by operating activities	$21,268	$8,954
Cash flows from investing activities:		
Capital expenditures for property, plant and equipment	(9,600)	(13,493)
Capital expenditures for intangible assets	(756)	(83)
Purchases of assets and investments	(3,613)	—
Purchase of debt securities	—	(15,250)
Net proceeds from sale of assets	—	4,800
Net cash used in investing activities	(13,969)	(24,026)
Cash flows from financing activities:		
Net proceeds from issuance of common shares	13,035	1,646
Changes in restricted cash	—	34,424
Repurchase and retirement of common shares	(43,885)	—
Excess income tax benefit on employee stock-based awards	105	54
Net cash (used in) provided by financing activities	(30,745)	36,124
Effect of exchange rate changes on cash	265	(1,921)
Net (decrease) increase in cash and cash equivalents	(23,181)	19,131
Cash and cash equivalents at the beginning of the period	63,663	36,815
Cash and cash equivalents at the end of the period	$40,482	$55,946

The accompanying notes form an integral part of these condensed consolidated financial statements

ORTHOFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

1. Nature of operations, basis of presentation and recently issued accounting pronouncements

Nature of operations

Orthofix International N.V. (together with its subsidiaries, the "Company") is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians. The Company is comprised of four reportable segments: BioStim, Biologics, Extremity Fixation and Spine Fixation supported by corporate activities.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair statement have been included. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 (the "2015 Form 10-K"). Operating results for the three and six months ended June 30, 2016, are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2016. The balance sheet at December 31, 2015, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates including those related to revenue recognition, contractual allowances, doubtful accounts, inventories, potential goodwill and intangible asset impairment, fair value measurements, litigation and contingent liabilities, income taxes, and shared-based compensation. Actual results could differ from these estimates. As permitted under U.S. GAAP, interim accounting for certain expenses, including income taxes, are based on full year forecasts.

Recently issued accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605), and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The standard was originally effective for public entities for annual and interim periods beginning after December 15, 2016. On July 9, 2015, the FASB agreed to defer the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date. The FASB also agreed to permit early adoption of the standard, but not before the original effective date. The standard is to be applied either retrospectively or as a cumulative effect adjustment as of the adoption date. The Company is currently evaluating the effect that adopting this new accounting guidance will have on the consolidated results of operations, cash flows, and financial position and developing processes and procedures to implement this guidance.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory. This ASU requires that an entity should measure inventory, unless accounted for under the last-in, first-out ("LIFO") or retail inventory methods, at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance will be effective prospectively for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the new guidance and does not expect it will have a material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This ASU requires entities to measure equity investments, except those accounted for under the equity method of accounting or those that result in consolidation of the investee, at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicability exception. The guidance will be effective prospectively for annual periods beginning after December 15, 2017, including interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the new guidance and does not expect it will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance is effective for interim and annual periods beginning after December 15, 2018, and will be applied at the beginning of the earliest period presented using a modified retrospective approach. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, accounting for forfeitures, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The guidance will be applied prospectively, retrospectively, or by means of a cumulative-effect adjustment to equity as of the beginning of the period in which the guidance is adopted, dependent upon the specific amendment that is adopted within the ASU. The Company is currently evaluating the effect that adopting this new guidance will have on the consolidated results of operations, cash flows, and financial position and developing processes and procedures to implement this guidance.

2. Inventories

The Company’s inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items, which is reviewed and updated on a periodic basis by management determined on a first-in, first-out basis. Work-in-process and finished products include the cost of materials, labor and other production costs. Finished products include field inventory which represents immediately saleable finished products that are in the possession of the Company’s independent sales representatives, and consignment inventory which represents immediately saleable finished products located at third party customers, such as distributors and hospitals. Deferred cost of sales result from transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not been met. Once the revenue recognition criteria have been met, both the revenues and associated cost of sales are recognized.

Inventories were as follows:

(U.S. Dollars, in thousands)	June 30, 2016	December 31, 2015
Raw materials	$7,070	$ 4,976
Work-in-process	9,442	5,087
Finished products	40,484	42,947
Deferred cost of sales	4,338	4,553
Total inventory	$61,334	$ 57,563

3. Long-term debt

On August 31, 2015, the Company, through certain of its subsidiaries entered into a Credit Agreement (the "Credit Agreement") with JPMorgan Chase Bank, N.A. ("JPMorgan"), as Administrative Agent, and certain lenders party thereto. The Credit Agreement provides for a five year $125 million secured revolving credit facility (the "Facility"). As of June 30, 2016, the Company has not made any borrowings under the Credit Agreement.

The Credit Agreement contains financial covenants requiring the Company to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0 based upon the Company's consolidated adjusted earnings. The Company is in compliance with all required financial covenants as of June 30, 2016. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated.

The Company had no borrowings and an unused available line of credit of €5.8 million ($6.4 million and $6.3 million) at June 30, 2016 and December 31, 2015, respectively, on its Italian line of credit. This unsecured line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

4. Derivative instruments

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. During 2016 and 2015, the Company made use of a foreign cross-currency swap agreement to manage cash flow exposure generated from foreign currency fluctuations.

The tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss). Any gains or losses reported in accumulated other comprehensive income are reclassified into earnings upon maturity.

(U.S. Dollars, in thousands)	Fair value: favorable (unfavorable)	Balance sheet classification
As of June 30, 2016		
Cross-currency swap	$ 2,374	Prepaid expenses and other current assets
Warrants	$ 321	Other long-term assets
As of December 31, 2015		
Cross-currency swap	$ 2,485	Prepaid expenses and other current assets
Warrants	$ 321	Other long-term assets

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Cross-currency swap unrealized gain, net of taxes	$50	$267	$76	$936
Warrants unrealized loss, net of taxes	$—	$4	$—	$—

5. Fair value measurements

The fair value of the Company’s financial assets and liabilities measured on a recurring basis were as follows:

(U.S. Dollars, in thousands)	June 30, 2016	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$1,599	$—	$1,599	$—

Treasury securities	521	521	—	—
Certificates of deposit	443	443	—	—
Derivative instruments	2,374	—	2,374	—
Debt securities	9,438	—	—	9,438
Total	$14,375	$964	$3,973	$9,438
Liabilities				
Deferred compensation plan	$(1,488)	$—	$(1,488)	$—
Total	$(1,488)	$—	$(1,488)	$—

(U.S. Dollars, in thousands)	December 31, 2015	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,622	$—	$1,622	$—
Treasury securities	495	495	—	—
Certificates of deposit	337	337	—	—
Derivative instruments	2,485	—	2,485	—
Debt securities	12,658	—	—	12,658
Total	$ 17,597	$832	$4,107	$12,658
Liabilities				
Deferred compensation plan	$ (1,503)	$—	$(1,503)	$—
Total	$ (1,503)	$—	$(1,503)	$—

Debt Securities

On March 4, 2015, the Company entered into an Option Agreement (the "Option Agreement") with eNeura, Inc. ("eNeura"), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provides the Company with an exclusive option to acquire eNeura (the "Option") during the 18-month period following the grant of the Option. In consideration for the Option, (i) the Company paid a non-refundable $0.3 million fee to eNeura, and (ii) eNeura issued a Convertible Promissory Note (the "eNeura Note") to the Company. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura Note will mature on the earlier of (i) March 4, 2019, or (ii) exercise of the Option. The interest is not due until the note matures and will be forgiven if the Company exercises the option. The investment is recorded in other long-term assets as an available for sale debt security and interest is recorded in interest income.

The fair value of the debt security is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. During the first quarter of 2016, the Company revised the estimated fair value which resulted in an impairment of $0.8 million. During the second quarter of 2016, the Company further revised its estimate based on current financial information and other assumptions. Revisions to current financial information had a significant negative impact on the valuation of the debt security resulting in an additional impairment of $3.0 million, which the Company recorded in accumulated other comprehensive loss as an unrealized loss on debt securities. The Company continues to classify the impairment as temporary in nature as the Company does not intend to sell the debt security nor does it believe that recoverability of the investment will not occur.

The following table provides a reconciliation of the beginning and ending balances for debt securities measured at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	
Balance at December 31, 2015	$12,658
Accrued interest income	640
Unrealized loss on debt securities	(3,860)
Balance at June 30, 2016	$9,438

6. Accumulated other comprehensive loss

Accumulated other comprehensive loss is comprised of foreign currency translation adjustments; the effective portion of the gain (loss) on the Company's cross-currency swap, which is designated and accounted for as a cash flow hedge; the unrealized gain (loss) on warrants; and the unrealized loss on the Company's debt securities. The components of

and changes in accumulated other comprehensive loss were as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Change in Fair Value of Derivatives	Change in Fair Value of Debt Securities	Accumulated Other Comprehensive Loss
Balance at December 31, 2015	$ (4,389)	$ 228	$ (2,071)	$ (6,232)
Unrealized gain on derivative instruments, net of tax of $51	—	76	—	76
Unrealized loss on debt securities, net of tax benefit of $1,391	—	—	(2,469)	(2,469)
Foreign currency translation adjustment (1)	651	—	—	651
Balance at June 30, 2016	$ (3,738)	$ 304	$ (4,540)	$ (7,974)

(1) As unremitted earnings generally remain indefinitely reinvested in the non U.S. dollar denominated foreign subsidiaries, no deferred taxes are recognized on the related foreign currency translation adjustment.

7. Earnings per share

For the three and six months ended June 30, 2016 and 2015, no adjustments were made to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net loss per common share computations.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Weighted average common shares-basic	18,147,681	18,769,415	18,312,781	18,750,804
Effect of dilutive securities:				
Unexercised stock options net of treasury share repurchase	—	220,164	—	—
Weighted average common shares-diluted	18,147,681	18,989,579	18,312,781	18,750,804

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares and performance-based restricted stock awards deemed not probable to vest are not included in the computation of diluted earnings per share. There were 792,149 outstanding awards and options not included in the diluted earnings per share computation for the three months ended June 30, 2015, because their inclusion was antidilutive.

Due to the Company having a net loss from continuing operations position for the three and six months ended June 30, 2016, there were 490,296 and 484,201 potentially dilutive shares excluded from the computation, respectively, as their effects would be antidilutive. Due to the Company having a net loss from continuing operations position for the six months ended June 30, 2015, there were 1,081,308 potentially dilutive shares excluded from the computation as their effects would be antidilutive.

8. Share-based compensation

All share-based compensation costs are measured at the grant date, based on the estimated fair value of the award, and recognized as expense in the condensed consolidated statements of operations over the requisite service period. The Company recognized $1.9 million and $3.9 million, respectively, of share-based compensation expense for the three and six months ended June 30, 2016 and $1.8 million and $3.6 million, respectively, for the three and six months ended June 30, 2015.

On June 30, 2014, the Company granted 99,600 performance-based restricted share awards to officers and certain employees. Vesting is based on achieving earnings targets in two consecutive rolling four quarter periods. As of June 30, 2016, no expense has been recognized for these contingent restricted share awards.

On June 30, 2015, the Company granted 68,750 performance-based restricted share awards to officers and on August 5, 2015, granted an additional 41,910 performance-based restricted share awards to other members of management. Vesting is based on achieving earnings and return on invested capital targets as of and for the years ended December 31, 2016, 2017 or 2018. As of June 30, 2016, no expense has been recognized for these contingent restricted share awards.

During the three months ended June 30, 2016 and 2015, there were 325,393 and 81,974 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the six months ended June 30, 2016 and 2015, there were 528,791 and 227,840 shares, respectively, of common stock issued related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

9. Income taxes

For the second quarter, our effective tax rate on continuing operations was (141.5%), or $3.7 million, as compared to 30.4%, or $1.8 million, for the same period in the prior year. Excluding the impact of various discrete tax charges, the effective tax rate on continuing operations for the second quarter of 2016 and 2015 was (131.6%) and 29.6%, respectively. For the first six months of 2016, our effective tax rate on continuing operations was 126.3%, or $8.0 million, as compared to (298.7%), or $2.7 million, for the same period in the prior year. Excluding the impact of various discrete tax charges, the effective tax rate on continuing operations for the first six months of 2016 and 2015 was 119.6% and (256.6%), respectively.

The primary factor affecting the Company’s effective tax rate for the three and six months ended June 30, 2016, was charges related to US Government Resolutions, which is non-deductible for tax purposes, and the impact of which is fully recognized in the second quarter. Other factors affecting the Company’s effective tax rate for the three and six months ended June 30, 2016, and June 30, 2015, were the Company’s mix of earnings among various tax jurisdictions, state taxes, and current period losses in certain jurisdictions for which the Company does not currently provide a tax benefit.

During the third quarter of 2015, the Internal Revenue Service commenced an examination of our federal income tax return for 2012. The Company cannot reasonably determine if this examination will have a material impact on our financial statements and cannot predict the timing regarding resolution of this tax examination.

10. Business segment information

The Company has four strategic business units ("SBUs"), which are comprised of BioStim, Biologics, Extremity Fixation, and Spine Fixation supported by corporate activities. The primary metric used in managing the Company is net margin, which is defined as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information.

The tables below present net sales for continuing operations by SBU reporting segment. Net sales include product sales and marketing service fees. Marketing service fees, which are recorded on a net basis, are comprised of fees earned for the marketing of Trinity Evolution®, Trinity ELITE® and Versashield™ in our Biologics segment.

	Three Months Ended June 30,		Reported	
(U.S. Dollars, in thousands)	2016	2015	Change	
BioStim	$44,758	$40,703	10.0	%
Biologics	14,256	15,274	(6.7	)%
Extremity Fixation	26,817	25,594	4.8	%
Spine Fixation	18,244	19,383	(5.9	)%
Total net sales	$104,075	$100,954	3.1	%

	Six Months Ended June 30,		Reported	
(U.S. Dollars, in thousands)	2016	2015	Change	
BioStim	$85,802	$78,403	9.4	%
Biologics	28,350	29,235	(3.0	)%
Extremity Fixation	51,526	47,409	8.7	%
Spine Fixation	37,076	35,669	3.9	%
Total net sales	$202,754	$190,716	6.3	%

The table below presents net margin, which is defined as gross profit less sales and marketing expense, by SBU reporting segment for the three and six months ended June 30, 2016 and 2015:

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2016	2015	Six Months Ended June 30, 2016	2015
Gross profit	$81,560	$79,044	$158,103	$149,467
Less: Sales and marketing	(46,037)	(42,946)	(90,853)	(87,231)
Total net margin	$35,523	$36,098	$67,250	$62,236
BioStim	18,577	16,787	34,988	30,800
Biologics	6,719	7,285	12,823	13,229
Extremity Fixation	8,162	9,149	15,340	16,165
Spine Fixation	2,203	3,173	4,539	2,644
Corporate	(138)	(296)	(440)	(602)
Total net margin	35,523	36,098	67,250	62,236
General and administrative	17,954	22,506	34,672	44,075
Research and development	6,792	6,451	14,428	12,296
Restatements and related costs	545	2,213	790	8,129
Charges related to U.S. Government resolutions	12,870	–	12,870	–
Operating (loss) income	$(2,638)	$4,928	$4,490	$(2,264)

11. Contingencies

The Company is party to outstanding legal proceedings, investigations and claims, as previously described in (i) Part I, Item 3, “Legal Proceedings,” of the 2015 Form 10-K and (ii) note 14 to the Company’s audited consolidated financial statements filed with the 2015 Form 10-K. The Company believes that it is unlikely that the outcome of any of these matters will have a material adverse effect on it and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on the Company’s net earnings (if any) in any particular quarter. However, the Company cannot predict with any certainty the final outcome of any of these legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims, and there can be no assurance that the ultimate resolution of any such matters will not have a material adverse impact on the Company’s consolidated financial position, results of operations, or cash flows.

In addition to the matters described in the paragraphs below and in the 2015 Form 10-K, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. To the extent losses related to these contingencies are both probable and reasonably estimable, the Company accrues appropriate amounts in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonably estimable. The Company believes losses with respect to these additional matters are individually and collectively immaterial as to a possible loss and range of loss.

Matters Related to the Audit Committee’s Review and the Restatement of Certain of our Consolidated Financial Statements

Audit Committee Review

In July 2013, the Audit Committee of our Board of Directors began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in a restatement of our previously filed consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 and the fiscal quarter ended March 31, 2013, as well as the restatement of certain financial information for the fiscal years ended December 31, 2009, 2008 and 2007. This restatement, which we completed and filed in March 2014, is referred to herein as the “Original Restatement.”

In connection with the Company’s preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain entries with respect to the previously filed financial statements contained in the filings containing the Original Restatement were not properly accounted for under U.S. GAAP. As a result, the Company determined in August 2014 to restate its previously filed consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 and quarterly reporting periods contained within the fiscal years ended December 31, 2013 and 2012, as well as the fiscal quarter ended March 31, 2014. This restatement, which we completed in March 2015, is referred to herein as the “Further Restatement.”

SEC Investigation

In connection with the initiation of the Audit Committee's independent review, we initiated contact with the staff of the Division of Enforcement of the SEC (the "SEC Enforcement Staff") in July 2013 to advise them of these matters. The Audit Committee and the Company, through respective counsel, have been in direct communication with the SEC Enforcement Staff regarding these matters. The SEC is conducting a formal investigation of these matters, and both the Company and the Audit Committee are cooperating fully with the SEC.

We have previously provided notice concerning our communications with the SEC to the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS-OIG") pursuant to our corporate integrity agreement with HHS-OIG (which agreement is described in Item 3 of our Form 10-K for the year ended December 31, 2015).

The Company is currently engaged in discussions with the SEC Enforcement Staff regarding a possible negotiated resolution of these matters as to the Company. Although such discussions remain ongoing, and any agreement reached between the SEC Enforcement Staff and the Company will be subject to approval by the full Commission, the Company has reached an agreement in principle with the SEC Enforcement Staff that any negotiated resolution will include a civil money penalty of approximately $8.3 million. Accordingly, we have recorded a charge of approximately $8.3 million during the second quarter of 2016 in connection with such amount. However, no assurance can be given that we will be able to achieve a final, definitive resolution with the SEC to resolve this matter on these or other terms, and the failure to resolve this matter on these or other terms could adversely affect our business and operations.

Securities Class Action Complaint

As described further in prior filings, in December 2015 the Company entered into a settlement agreement, subject to court approval, in connection with a securities class action complaint filed against the Company in the United States District Court for the Southern District of New York (Tejinder Singh v. Orthofix International N.V., et al. (No.:1:13-cv-05696-JGK)), which complaint arose out of the restatement of our prior financial statements and the matters described above. The full amount of the settlement was paid into a settlement fund by the Company's insurer in February of 2016.

On April 29, 2016, the court approved the settlement and entered final judgment, releasing all claims by class members arising out of the facts alleged in the pleadings and dismissing the action with prejudice.

Deferred Prosecution Agreement and Review of Potential Improper Payments Involving Brazil Subsidiary

In 2012, the Company entered into definitive agreements with the U.S. Department of Justice (the "DOJ") and the SEC agreeing to settle a self-initiated and self-reported internal investigation of our Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the U.S. Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, we entered into a three-year deferred prosecution agreement ("DPA") with the DOJ and a consent to final judgment (the "Consent") with the SEC. Under the DPA, the DOJ agreed not to pursue any criminal charges against us in connection with the Promeca matter if we complied with the terms of the DPA. The DPA took note of our self-reporting of this matter to the DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by us. The DPA and the Consent collectively required, among other things, that with respect to anti-bribery compliance matters we would continue to cooperate fully with the government in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, we represented that we have implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws, which includes a system of internal controls. We periodically reported to the government during the terms of the DPA and Consent regarding such remediation and implementation of compliance measures.

In August 2013, during the terms of the DPA and Consent, the Company's internal legal department was notified of certain allegations involving potential improper payments with respect to its Brazilian subsidiary, Orthofix do Brasil Ltda. The Company engaged outside counsel to assist in the review of these allegations, focusing on compliance with applicable anti-bribery laws, including the FCPA. Consistent with the provisions of these agreements, the Company contacted both the DOJ and the SEC Enforcement Staff in August 2013 to voluntarily self-report the Brazil-related allegations.

On June 15, 2015, the Company and the DOJ agreed to extend the term of the DPA for two months (through September 17, 2015) to permit the DOJ additional time to evaluate the Company's compliance with the internal controls and compliance undertakings in the DPA and to further investigate the Brazil-related allegations. On September 17, 2015, the DOJ extended the term of the DPA for an additional ten months (through July 17, 2016), stating that the Company's efforts to comply with the internal controls and compliance requirements of the DPA during the first eighteen months of the DPA were insufficient. On July 17, 2016, the DPA expired. The terms of the DPA require that DOJ notify the court and file a dismissal of the underlying Promeca-related case within 30 days of such expiration. This dismissal was filed on July 28, 2016. Since the self-report regarding allegations in Brazil, the Company has cooperated fully with the DOJ's investigation of those allegations.

The Company also has fully cooperated with the SEC's investigations of the allegations in Brazil. We are currently engaged in discussions with the SEC Enforcement Staff regarding a resolution of the Brazil-related allegations as they relate to the SEC's jurisdiction. The Company has recorded a charge of $4.6 million in the second quarter of 2016 to establish an accrual, which the Company believes represents the minimum range of loss, in connection with a potential negotiated resolution to this matter. Based on information available at this time, the Company estimates that the final resolution to the matter could result in an additional loss of up to $1.5 million in excess of the loss accrued. The Company will continue to evaluate the accrual pending final resolution of the matter and the related settlement discussions with the government.

Matters Related to the Company's Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, we sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street") pursuant to a stock purchase agreement (the "Breg SPA"). Under the terms of the Breg SPA, upon closing of the sale, the Company and its subsidiary, Orthofix Holdings, Inc., agreed to indemnify Water Street and Breg with respect to certain specified matters, including the following:

- Breg was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008. Since 2008, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called "chondrolysis." The Company incurred losses for settlements and judgments in connection with these matters during the first six months of 2016 of $0.5 million as

compared to none in the first six months of 2015. In addition, several cases remain outstanding for which the Company currently cannot reasonably estimate the possible loss, or range of loss.

- At the time of its divestiture by us, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units or who would not have purchased the units had they known they could be injured. In September 2014, the Company entered into a master settlement agreement resolving all pending pre-close claims. Pursuant to the terms of the settlement agreement, the Company paid approximately $1.3 million, and additional amounts owed under the settlement were paid directly by the Company's insurance providers. These amounts paid by the Company were recorded as an expense in discontinued operations during the fiscal quarter ended June 30, 2014. Remaining cold therapy claims include a putative consumer class of individuals who did not suffer physical harm following use of the devices, and an appeal of an adverse July 2012 California jury verdict and a post-close cold therapy claim pending in California state court. As of June 30, 2016, we have accrued $5.8 million for the July 2012 verdict and post-close cold therapy liabilities; however, actual liability could be higher or lower than the amount accrued. The putative class action is at an early stage and the Company currently cannot reasonably estimate the possible loss, or range of loss.

Charges incurred as a result of this indemnification are reflected as discontinued operations in our Condensed Consolidated Statements of Operations and Comprehensive Loss.

12. Share repurchase plan

The Company's Board of Directors authorized a share repurchase plan in the fourth quarter of 2015, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. Under the program, common share repurchases are expected to consist primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, as amended, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company's secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. During the quarter ended June 30, 2016, the Company repurchased 403,688 shares of common stock for $17.4 million with an average price per share of $43.16 which were all retired upon repurchase. As of June 30, 2016, there was $19.5 million remaining under this share repurchase authorization. From July 1, 2016, to July 29, 2016, the Company has made additional repurchases of 45,108 shares for an amount equal to $2.1 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis addresses the results of our operations which are based upon the condensed consolidated financial statements included herein, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), for the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015. These discussions should be read in conjunction with our historical consolidated financial statements and related notes thereto and the other financial information included in this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016.

General

We are a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, TX, the Company has four strategic business units (SBUs) that include BioStim, Biologics, Extremity Fixation and Spine Fixation, which are described in further detail below under "Business Segments." Orthofix products are widely distributed via the Company's sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal Transplant Foundation and the Texas Scottish Rite Hospital for Children.

Our strategy in 2016 is built upon the following key objectives:

(i) Sales Channel Expansion and Optimization – Our objective for 2016 is to increase revenue for each of our SBUs at a faster rate than their respective markets by growing and optimizing our sales force while expanding our product portfolio with new and innovative products through both internal development and technology licensing and acquisitions. During the second quarter of 2016, we launched Firebird NXG in our Spine SBU, our fourth generation Firebird pedicle screw system, which provides a lower profile body and simplifies instrumentation, thus improving upon this already versatile system. Our Spine SBU also launched our second generation LoneStar Cervical Standalone System with serrated radial fixation ribs as well as the Stabilink MIS interlaminar stabilization system. We believe that our product pipeline is robust and we expect our recent product launches, and other products expected to launch in the future, to be drivers of our top line revenue growth in the foreseeable future.

(ii) Operating Margin Improvement – With our infrastructure improvement projects now nearing completion, we plan to focus on continuous improvement initiatives in all areas of the company to become more effective and efficient. We expect the resulting cost savings, coupled with absorption of fixed costs from an expected increase in net sales, to drive operating margins higher over the next four to six quarters.

(iii) Investment in Clinical Research – In order to ensure the long-term success of our Company, we plan on continuing to invest significant resources in clinical research, particularly for our regenerative technologies. In 2016, we plan to initiate or continue work on a variety of clinical studies supporting both our existing products and to identify new indications for our PEMF technologies, such as for the treatment of rotator cuff injuries and knee osteoarthritis. Additionally, we plan to continue to evaluate and initiate new pre-clinical and clinical studies throughout the year for our other businesses and technologies to drive long-term growth. This quarter, a prospective clinical trial of Trinity Evolution in one-level anterior cervical discectomies and fusions ("ACDFs") was published in the European Spine Journal, showing fusion success rates of 93% at twelve months. In addition, a retrospective study was also recently published on Trinity Evolution in one-level and two-level instrumented lumbar posterolateral fusions, which showed fusion success rates at one year of 90%. We are also currently enrolling a multi-center, prospective, Trinity Elite study in this posterolateral model and plan to continue to invest in clinical research to demonstrate the benefits of using our Trinity tissue forms, made available through our partnership with MTF, in these challenging procedures.

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Business Segments

The table below presents net margin, a Non-GAAP measure, which is defined as gross profit less sales and marketing expense, by SBU reporting segment for the three and six months ended June 30, 2016 and 2015:

	Three Months Ended		Six Months Ended	
(U.S. Dollars, in thousands)	June 30, 2016	2015	June 30, 2016	2015
Gross profit	$81,560	$79,044	$158,103	$149,467
Less: Sales and marketing	(46,037)	(42,946)	(90,853)	(87,231)
Total net margin	$35,523	$36,098	$67,250	$62,236
BioStim	18,577	16,787	34,988	30,800
Biologics	6,719	7,285	12,823	13,229
Extremity Fixation	8,162	9,149	15,340	16,165
Spine Fixation	2,203	3,173	4,539	2,644
Corporate	(138)	(296)	(440)	(602)
Total net margin	35,523	36,098	67,250	62,236
General and administrative	17,954	22,506	34,672	44,075
Research and development	6,792	6,451	14,428	12,296
Restatements and related costs	545	2,213	790	8,129
Charges related to U.S. Government resolutions	12,870	–	12,870	–
Operating (loss) income	$(2,638)	$4,928	$4,490	$(2,264)

BioStim

The BioStim SBU manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). These devices utilize pulsed electromagnetic field technology, which is supported by strong basic mechanism of action data in the scientific literature and as well as strong level one randomized controlled clinical trials in the medical literature. Current research and clinical studies are also underway to identify potential new clinical indications. This SBU uses distributors and sales representatives to sell its devices to hospitals, doctors and other healthcare providers, primarily in the U.S.

Biologics

The Biologics SBU provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of the Company’s regeneration tissue forms. Biologics markets its tissues through a network of distributors, independent sales representatives, and affiliates to supply to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with the Musculoskeletal Transplant Foundation allows us to exclusively market our Trinity Evolution® and Trinity ELITE® tissue forms for musculoskeletal defects to enhance bony fusion.

Extremity Fixation

The Extremity Fixation SBU offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates to sell orthopedic products to hospitals, doctors, and other health providers, globally.

Spine Fixation

The Spine Fixation SBU specializes in the design, development and marketing of a broad portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors, sales representatives, and affiliates to sell spine products to hospitals, doctors, and other healthcare providers, globally.

Corporate

Corporate activities are comprised of the operating expenses, including share-based compensation of Orthofix International N.V. and its holding company subsidiaries, along with activities not necessarily identifiable within the four SBUs.

The following table presents certain items in our condensed consolidated statements of operations as a percent of total net sales for the periods indicated:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	21.6	21.7	22.0	21.6
Gross profit	78.4	78.3	78.0	78.4
Operating expenses:				
Sales and marketing	44.2	42.5	44.8	45.7
General and administrative	17.3	22.3	17.1	23.1
Research and development	6.5	6.4	7.1	6.5
Restatements and related costs	0.5	2.2	0.4	4.3
Charges related to U.S. Government resolutions	12.4	—	6.4	—
Operating (loss) income	(2.5)	4.9	2.2	(1.2)
Net (loss) income	(7.1)	3.5	(1.7)	(2.5)

Three and Six Months Ended June 30, 2016 Compared to Three and Six Months Ended June 30, 2015

Net Sales

The tables below present net sales by SBU reporting segment for the three and six months ended June 30, 2016 and 2015. Constant currency, a Non-GAAP measure presented below, measures actual performance using foreign currency rates from the comparable, prior-year period, to present actuals at comparable rates. Constant currency is used by the Company’s management to compare revenues with and without the impact of changes in foreign currencies.

	Three Months Ended June 30,			
			Reported	Constant Currency
(U.S. Dollars, in thousands)	2016	2015	Change	Change
BioStim	$44,758	$40,703	10.0 %	10.0 %
Biologics	14,256	15,274	(6.7)%	(6.7)%

Extremity Fixation	26,817	25,594	4.8	%	4.8	%
Spine Fixation	18,244	19,383	(5.9	)%	(5.8	)%
Total net sales	$104,075	$100,954	3.1	%	3.1	%

	Six Months Ended June 30,					
(U.S. Dollars, in thousands)	2016	2015	Reported Change		Constant Currency Change	
BioStim	$85,802	$78,403	9.4	%	9.4	%
Biologics	28,350	29,235	(3.0	)%	(3.0	)%
Extremity Fixation	51,526	47,409	8.7	%	12.2	%
Spine Fixation	37,076	35,669	3.9	%	4.1	%
Total net sales	$202,754	$190,716	6.3	%	7.2	%

For the second quarter, net sales increased by $3.1 million, or 3.1%, when compared to the same period of the prior year. For the first six months of 2016, net sales increased by $12.0 million, or 6.3%, when compared to the same period of the prior year. Excluding the impact of foreign currency, net sales for the first six months increased by approximately $13.8 million, or 7.2%, when compared to the same period in the prior year.

Net Sales by SBU

For the second quarter, net sales in our BioStim SBU increased $4.1 million, or 10.0%, as compared to the same period in the prior year. For the first six months of 2016, net sales in our BioStim SBU increased $7.4 million, or 9.4%, as compared to the same period in the prior year. The growth was primarily driven by increased order counts from an expanding customer base and our order to cash process improvements that increased the overall percentage that we collect on orders and therefore increased net sales.

For the second quarter, net sales in our Biologics SBU decreased $1.0 million, or 6.7%, as compared to the same period in the prior year. For the first six months of 2016, net sales in our Biologics SBU decreased $0.9 million, or 3.0%, as compared to the same period in the prior year. These decreases were primarily driven by a decrease in volume for our Trinity Elite® tissue form due to the exclusion from a large national hospital account and additional competing product offerings.

For the second quarter, net sales in our Extremity Fixation SBU increased $1.2 million, or 4.8%, as compared to the same period in the prior year. This increase was primarily driven by growth in the U.S. as a result of the increased adoption of our TL-HEX TrueLok Hexapod System® (“TL-HEX™”) and the addition of new distributors. For the first six months of 2016, net sales in our Extremity Fixation SBU increased $4.1 million, or 8.7%, as compared to the same period in the prior year, despite a negative impact from foreign currency translation of $1.7 million. Excluding the impact of foreign currency, net sales in the first six months of 2016 for our Extremity Fixation SBU increased $5.8 million, or 12.2%, primarily driven by growth in the U.S. as a result of the increased adoption of our TL-HEX™ system and higher than expected international cash collections.

For the second quarter, net sales in our Spine Fixation SBU decreased $1.1 million, or 5.9%, as compared to the same period in the prior year. This decrease was primarily due to a loss of several key surgeon customers in the U.S., the timing of international cash collections and exclusion from a large national hospital account. For the first six months of 2016, net sales in our Spine Fixation SBU increased $1.4 million, or 3.9%, as compared to the same period in the prior year. These increases were primarily due to higher international sales.

Gross Profit

	Three Months Ended		Six Months Ended	
(U.S. Dollars, in thousands)	June 30, 2016	2015	June 30, 2016	2015
Net sales	$104,075	$100,954	$202,754	$190,716
Cost of sales	22,515	21,910	44,651	41,249
Total gross profit	$81,560	$79,044	$158,103	$149,467

For the second quarter, gross profit increased by $2.5 million, or 3.2%, and increased $8.6 million, or 5.8% in the first six months of 2016, when compared to the same period in the prior year. The increase in gross profit was primarily driven by the increase in net sales. Gross margin was 78.4% in the second quarter of 2016 compared to 78.3% for the same period of the prior year and was 78.0% in the first six months of 2016 compared to 78.4% for the same period of the prior year. The modest decrease in gross margin percentage for the year to date period was driven by the increased proportion of net sales of our fixation products, which have lower margins compared to our regenerative solutions.

Operating Expenses

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2016	2015	Six Months Ended June 30, 2016	2015
Sales and marketing	$46,037	$42,946	$90,853	$87,231
General and administrative	17,954	22,506	34,672	44,075
Research and development	6,792	6,451	14,428	12,296
Restatements and related costs	545	2,213	790	8,129
Charges related to U.S. Government resolutions	12,870	–	12,870	–
Total operating expenses	$84,198	$74,116	$153,613	$151,731

Sales and Marketing Expense

Sales and marketing expense increased $3.1 million, or 7.2%, in the second quarter and increased $3.6 million, or 4.2%, in the first six months of 2016, when compared to the same period in the prior year. These increases were primarily due to lower than usual sales and marketing expenses in the prior year period due to the restructuring of the U.S. Extremity Fixation sales management organization; increased costs for surgeon education and workshops; and an increase in bad debt expense. As a percent of net sales, sales and marketing expense was 44.2% and 42.5% in the second quarter of 2016 and 2015, respectively. As a percent of net sales, sales and marketing expense was 44.8% and 45.7% in the first six months of 2016 and 2015, respectively. The increase in sales and marketing expense as a percentage of sales for the quarter is primarily driven lower than usual sales and marketing expenses in the prior year due to the restructuring of the U.S. Extremity Fixation sales management organization. The decrease in sales and marketing expense as a percentage of sales for the year to date period is driven by a decrease in commissions as a percentage of net sales and improved operating leverage of our fixed costs.

General and Administrative Expense

General and administrative expense, inclusive of amortization of intangible assets, decreased $4.6 million, or 20.2%, in the second quarter and decreased $9.4 million, or 21.3%, in the first six months of 2016, when compared to the same period in the prior year. The decrease for the quarter to date period was driven by a decrease in legal costs of $1.1 million largely from a legal judgment incurred in the prior year, a decrease in professional and consulting fees of $1.0 million, and decreased software maintenance costs. The decrease for the year to date period was primarily driven by a decrease in professional and consulting fees of $4.7 million largely associated with Project Bluecore as the majority of initiatives have been completed, decreased legal costs of $1.1 million due to a legal judgment incurred in the prior year and reductions in controllable expenses. As a percent of net sales, general and administrative expense was 17.3% and 22.3% in the second quarter of 2016 and 2015, respectively, and 17.1% and 23.1% in the first six months of 2016 and 2015, respectively.

Research and Development Expense

Research and development expense increased $0.3 million, or 5.3%, in the second quarter and increased $2.1 million, or 17.3%, in the first six months of 2016, when compared to the same period in the prior year. The increase for the quarter to date period was primarily driven by increased costs of $0.6 million associated with the Company’s ongoing clinical trials. The increase for the year to date period was primarily driven by a $1.3 million investment to expand the processing and storage capabilities of MTF, the supplier of our Trinity Evolution® and Trinity ELITE® tissue forms and increased compensation and benefit costs of $0.5 million. As a percent of net sales, research and development

expense was 6.5% and 6.4% in the second quarter of 2016 and 2015, respectively, and 7.1% and 6.4% in the first six months of 2016 and 2015, respectively.

Restatements and Related Costs

As part of the restatements of our consolidated financial statements, the Company incurred $0.5 million and $0.8 million of charges related to these activities for the second quarter and first six months of 2016 respectively. In comparison, the Company incurred $2.2 million and $8.1 million for the same periods in the prior year. The costs incurred in 2016 are primarily continuing legal fees incurred as part of the SEC Investigation, resulting from the Original and Further Restatements. The costs incurred in 2015 were related to our Further Restatement filed in March 2015 and legal costs from the resulting SEC investigation and class action complaint.

Charges Related to U.S. Government Resolutions

The Company recorded $12.9 million for the second quarter and the first six months of 2016. These charges relate to our ongoing settlement discussions with the Division of Enforcement of the SEC related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments with respect to our Brazil-based subsidiary. For additional information, see Note 11 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Non-operating Income and Expense

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Interest (expense) income, net	$(113)	$74	$(151)	$(198)
Other income, net	147	853	1,980	1,544
Total non-operating income	$34	$927	$1,829	$1,346

Interest Expense, Net

Interest expense, net was $0.1 million in the second quarter compared to interest income, net of $0.1 million for the same period in the prior year. Interest expense, net was $0.2 million for the first six months of 2016 and for the same period in the prior year.

Other Income, Net

Other income, net was $0.1 million in the second quarter as compared to other income of $0.9 million for the same period in the prior year. Other income, net was $2.0 million for the first six months of 2016 compared to other income, net of $1.5 million for the same period in the prior year. The quarter to date decrease was primarily driven by an unfavorable impact of foreign exchange rates of $0.5 million when compared to the prior year. The year to date increase was primarily due to a favorable impact of foreign exchange rates of $3.7 million as compared to the prior year, offset by a $3.1 million gain on the sale of the Company's Tempus™ Cervical Plate product line in 2015.

Income Taxes

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2016	2015	2016	2015
Income tax expense from continuing operations	$(3,685)	$(1,778)	$(7,979)	$(2,742)
Effective tax rate	(141.5)%	30.4 %	126.3 %	(298.7)%

For the second quarter, our effective tax rate on continuing operations was (141.5%), or $3.7 million, as compared to 30.4%, or $1.8 million, for the same period in the prior year. Excluding the impact of various discrete tax charges, the effective tax rate on continuing operations for the second quarter of 2016 and 2015 was (131.6%) and 29.6%, respectively. In the first six months of 2016, our effective tax rate on continuing operations was 126.3%, or $8.0

million, as compared to (298.7%), or $2.7 million, for the same period in the prior year. Excluding the impact of various discrete tax charges, the effective tax rate on continuing operations for the first six months of 2016 and 2015 was 119.6% and (256.6%), respectively. The primary factor affecting the Company's effective tax rate for the three and six months ended June 30, 2016, was charges related to U.S. Government resolutions, which is non-deductible for tax purposes, and the impact of which is fully recognized in the second quarter. Other factors affecting the Company's effective tax rate for the three and six months ended June 30, 2016, were the Company's mix of earnings among various tax jurisdictions, state taxes, and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

Discontinued Operations

Net loss from discontinued operations was approximately $1.1 million and $1.8 million for the second quarter and for the first six months of 2016, respectively, as compared to net loss of $0.5 million and $1.1 million for the same periods in the prior year. The activity in discontinued operations is comprised of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to our former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters.

Liquidity and Capital Resources

Cash Flow

Cash and cash equivalents at June 30, 2016, was $40.5 million compared to cash and cash equivalents of $63.7 million at December 31, 2015.

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2016	2015	Change
Net cash provided by operating activities	$21,268	$8,954	$12,314
Net cash used in investing activities	(13,969)	(24,026)	10,057
Net cash (used in) provided by financing activities	(30,745)	36,124	(66,869)
Effect of exchange rate changes on cash	265	(1,921)	2,186
Net (decrease) increase in cash and cash equivalents	$(23,181)	$19,131	$(42,312)

Operating Activities

Net cash provided by operating activities is comprised of net income (loss), non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation and deferred income taxes) and changes in working capital. Net loss decreased $1.3 million to net loss of $3.5 million for the six months ended June 30, 2016, from net loss of $4.8 million for the comparable period in the prior year. Non-cash adjustments to reconcile net income (loss) to net cash provided by operating activities for the six months ended June 30, 2016 increased $2.1 million to $16.5 million compared to $14.4 million in the same period of 2015. Working capital accounts provided $8.2 million of cash for the six months ended June 30, 2016, and used $0.6 million for the six months ended June 30, 2015, specifically driven by trade accounts receivable, inventories, and trade accounts payable.

Investing Activities

Net cash used in investing activities decreased for the six months ended June 30, 2016 due to the purchase of debt securities in connection with the Option Agreement with eNeura of $15.3 million in the first quarter of 2015 and a decrease in capital expenditures of $3.2 million. These decreases were offset by proceeds from the sale of assets of $4.8 million in the prior year, the purchase of certain inventory and intellectual property assets of $2.6 million in the second quarter of 2016, and an increase in our investment in Bone Biologics of $1.0 million in the first quarter of 2016.

Financing Activities

Net cash from financing activities decreased for the six months ended June 30, 2016 largely due to the repurchases of the Company’s stock under the share repurchase plan authorized by the Board of Directors and the removal of the

restricted cash requirement associated with the Company's credit facility in the prior year. During the first six months of 2016, the Company repurchased approximately 1.1 million shares for $43.9 million. The removal of the restricted cash requirement associated with the Company's credit facility also resulted in a decrease in cash flows from financing activities of $34.4 million when compared to the prior year. During the six months ended June 30, 2016 and 2015, we also received proceeds of $13.0 million and $1.6 million, respectively, from the issuance of common stock.

Infrastructure Initiative

In 2014, we initiated project Bluecore to improve the reliability and efficiency of our systems, processes and reporting as well as drive down our overhead expenses. In addition to re-implementing our Oracle ERP platform in the U.S. and Italy, this initiative improved supply chain management, simplified finance and accounting procedures and allowed the Company to move to less manual processes with fewer redundancies. The Company re-implementation of its Oracle ERP platform was placed into production in the

U.S. and Italy in the second and third quarters of 2016, respectively. For the six months ended June 30, 2016, the Company spent $5.4 million pursuant to this initiative, $3.2 million of which was capitalized. Over the life of the project, the Company has spent $27.5 million, of which $18.6 million has been capitalized. We expect to spend an additional $1.9 million over the remainder of the project.

Credit Facilities

There have been no material changes to our debt instruments as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Share Repurchase Plan

In August 2015, the Company's Board of Directors authorized a share repurchase plan, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. Under the program, common share repurchases are expected to consist primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, as amended, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company's secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. As of June 30, 2016, the Company had repurchased a cumulative total of 1,373,938 shares of common stock for $55.5 million under this authorization. From July 1, 2016 to July 29, 2016, the Company has made additional repurchases of 45,108 shares for an amount equal to $2.1 million.

Other

The Company holds an exclusive option to acquire eNeura, a privately held medical technology company, during an 18-month period, which expires in September of 2016. If the Company exercises the option to acquire eNeura, the Company will pay to former eNeura shareholders up to $65 million.

The Company is currently engaged in settlement discussions with the SEC Enforcement Staff regarding the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments involving our Brazil-based subsidiary. Accordingly, the Company has accrued, but not paid as of June 30, 2016, a charge of approximately $12.9 million in connection with these matters. The Company may draw on its credit facility to pay amounts due once a final, definitive resolution of these matters is achieved. For additional information, see Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements.

For information regarding Contingencies, see Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

As a multinational company, we are subject to certain market risks, including foreign currency. We consider a variety of practices to manage these market risks. For information regarding the derivative instruments the Company owns to manage these risks, see Note 4 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of June 30, 2016, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors.

Contractual Obligations

There have been no material changes in any of our material contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Critical Accounting Policies and Estimates

There have been no material changes to our critical accounting policies, as described in our Annual Report on Form 10-K for the year ended December 31, 2015.

Recently Issued Accounting Pronouncements

See Note 1 of the Notes to the Unaudited Condensed Consolidated Financial Statements for detailed information regarding the status of recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a multinational company, we are subject to certain market risks including foreign currency, interest rate, and concentration of credit. We consider a variety of practices to manage these market risks. There have been no material changes to our market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act")) designed to provide reasonable assurance that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. These include controls and procedures designed to ensure that this information is accumulated and communicated to the Company's management, including its President and Chief Executive Officer and its Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Management, with the participation of the President and Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2016. Based on this evaluation, the Company's President and Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of June 30, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in the Company’s internal control over financial reporting during the quarter ended June 30, 2016, that have materially affected or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, see Note 11 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein, which is incorporated by reference into this Part II, Item 1.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Stock Repurchases Made in the Quarter

Under our share repurchase plan, repurchases are being made from time to time in the open market based on market conditions, securities law limitations and other factors. The following table sets forth information with respect to shares of our common stock purchased by the Company during the second quarter of 2016.

Period	Total Number of Shares Purchased	Average price Paid Per Share	Total Number of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Yet to be Purchased under Approved Stock Repurchase Program
April 2016	158,960	$ 42.28	158,960	$30,240,519
May 2016	134,488	$ 43.51	134,488	$24,389,041
June 2016	110,240	$ 43.99	110,240	$19,539,382
Total	403,688	$ 43.16	403,688	$19,539,382

Item 3. Defaults Upon Senior Securities

There are no matters to be reported under this heading.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

There are no matters to be reported under this heading.

Item 6. Exhibits

10.1	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.2	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.3	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.4	Form of 2016 Employee Performance Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.5	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.6	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.7	Form of Time-Based Vesting Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (annual grant) (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.8	Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (initial grant) (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.9	Letter Agreement, dated July 7, 2016, between Jeffrey M. Schumm, Orthofix International N.V. and Orthofix Inc. (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2016 and incorporated here by reference).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certifications of each of the Chief Executive Officer and Chief Financial Officer.
101*	The following materials from this Form 10-Q, formatted in Extensible Business Reporting Language ("XBRL"): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes,

detail tagged.

*Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

ORTHOFIX INTERNATIONAL N.V.

Date: August 1, 2016 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: August 1, 2016 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer