ORTHOFIX INTERNATIONAL N V
Form 10-Q
August 07, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

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	98-1340767

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7 Abraham de Veerstraat Curaçao (Address of principal executive offices)	Not applicable (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. Yes No

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

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

Large Accelerated filer	Accelerated filer
Non-Accelerated filer (Do not check if a smaller reporting company)	Smaller Reporting Company
	Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 4, 2017, 18,170,923 shares of common stock were issued and outstanding.

Table of Contents

		Page
PART I	FINANCIAL INFORMATION	
Item 1.	Financial Statements	4
	Condensed Consolidated Balance Sheets as of June 30, 2017, and December 31, 2016	4
	Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2017, and 2016	5
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016	6
	Notes to the Unaudited Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	20
Item 4.	Controls and Procedures	20
PART II	OTHER INFORMATION	
Item 1.	Legal Proceedings	21
Item 1A.	Risk Factors	21
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	21
Item 3.	Defaults Upon Senior Securities	21
Item 4.	Mine Safety Disclosures	21
Item 5.	Other Information	21
Item 6.	Exhibits	22
SIGNATURES		23

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), 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 c terminology. 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 Form 10-K for the year ended December 31, 2016, to reflect new information, the occurrence of future events or circumstances or otherwise.

Trademarks

Solely for convenience, our trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

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, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 44,330	$ 39,572
Restricted cash	—	14,369
Accounts receivable, net of allowances of $8,480 and $8,396, respectively	61,213	57,848
Inventories	75,869	63,346
Prepaid expenses and other current assets	17,192	19,238
Total current assets	198,604	194,373
Property, plant and equipment, net	46,651	48,916
Patents and other intangible assets, net	9,508	7,461
Goodwill	53,565	53,565
Deferred income taxes	42,685	47,325
Other long-term assets	16,664	20,463
Total assets	$ 367,677	$ 372,103
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 14,245	$ 14,353
Other current liabilities	50,858	69,088
Total current liabilities	65,103	83,441
Other long-term liabilities	25,627	25,185
Total liabilities	90,730	108,626
Contingencies (Note 6)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,119,430 and 17,828,155 issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	1,812	1,783
Additional paid-in capital	211,990	204,095
Retained earnings	65,378	64,179
Accumulated other comprehensive loss	(2,233)	(6,580)
Total shareholders' equity	276,947	263,477
Total liabilities and shareholders' equity	$ 367,677	$ 372,103

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

4

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

	Three Months Ended June 30,		Six Months Ended June 30,	
(Unaudited, U.S. Dollars, in thousands, except share and per share data)	2017	2016	2017	2016
Net sales	$108,942	$104,075	$211,680	$202,754
Cost of sales	23,177	22,516	45,758	44,653
Gross profit	85,765	81,559	165,922	158,101
Sales and marketing	50,471	46,043	99,003	90,865
General and administrative	20,409	18,545	38,691	35,550
Research and development	6,887	6,796	14,311	14,436
Charges related to U.S. Government resolutions	—	12,870	—	12,870
Operating income (loss)	7,998	(2,695)	13,917	4,380
Interest income (expense), net	76	(113)	121	(151)
Other income (expense), net	585	147	(3,763)	1,980
Income (loss) before income taxes	8,659	(2,661)	10,275	6,209
Income tax expense	(3,924)	(3,685)	(7,848)	(7,979)
Net income (loss) from continuing operations	4,735	(6,346)	2,427	(1,770)
Discontinued operations (Note 6)				
Loss from discontinued operations	(1,300)	(1,572)	(1,827)	(2,562)
Income tax benefit	418	474	599	728
Net loss from discontinued operations	(882)	(1,098)	(1,228)	(1,834)
Net income (loss)	$3,853	$(7,444)	$1,199	$(3,604)
Net income (loss) per common share—basic				
Net income (loss) from continuing operations	$0.26	$(0.35)	$0.13	$(0.10)
Net loss from discontinued operations	(0.05)	(0.06)	(0.06)	(0.10)
Net income (loss) per common share—basic	$0.21	$(0.41)	$0.07	$(0.20)
Net income (loss) per common share—diluted				
Net income (loss) from continuing operations	$0.26	$(0.35)	$0.13	$(0.10)
Net loss from discontinued operations	(0.05)	(0.06)	(0.06)	(0.10)
Net income (loss) per common share—diluted	$0.21	$(0.41)	$0.07	$(0.20)
Weighted average number of common shares:				
Basic	18,050,551	18,147,681	18,015,308	18,312,781
Diluted	18,343,038	18,147,681	18,288,050	18,312,781
Other comprehensive income, before tax				
Unrealized gain on derivative instrument	–	79	–	127
Unrealized loss on debt securities	–	(3,036)	(3,220)	(3,860)
Reclassification adjustment for loss on debt securities in net income	–	–	5,585	–
Currency translation adjustment	2,648	(570)	2,882	651
Other comprehensive income before tax	2,648	(3,527)	5,247	(3,082)
Income tax related to items of other comprehensive loss	–	1,065	(900)	1,340

Other comprehensive income, net of tax	2,648	(2,462)	4,347	(1,742)
Comprehensive income (loss)	$6,501	$(9,906)	$5,546	$(5,346)

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

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

	Six Months Ended June 30,	
(Unaudited, U.S. Dollars, in thousands)	2017	2016
Cash flows from operating activities		
Net income (loss)	$1,199	$(3,604)
Adjustments to reconcile net income (loss) to net cash from operating activities		
Depreciation and amortization	10,447	10,003
Amortization of debt costs and other assets	719	941
Provision for doubtful accounts	820	957
Deferred income taxes	4,284	687
Share-based compensation	5,492	4,012
Other-than-temporary impairment on debt securities	5,585	—
Other	572	772
Changes in operating assets and liabilities		
Restricted cash	14,369	—
Accounts receivable	(3,787)	2,443
Inventories	(11,119)	(2,974)
Prepaid expenses and other current assets	2,199	340
Accounts payable	(950)	(2,879)
Other current liabilities	(19,407)	10,664
Other long-term assets and liabilities	(696)	11
Net cash from operating activities	9,727	21,373
Cash flows from investing activities		
Capital expenditures for property, plant and equipment	(7,035)	(9,600)
Capital expenditures for intangible assets	(1,558)	(756)
Other investing activities	474	(3,613)
Net cash from investing activities	(8,119)	(13,969)
Cash flows from financing activities		
Proceeds from issuance of common shares	5,282	14,828
Payments related to withholdings for share-based compensation	(2,851)	(1,793)
Repurchase and retirement of common shares	—	(43,885)
Net cash from financing activities	2,431	(30,850)
Effect of exchange rate changes on cash	719	265
Net change in cash and cash equivalents	4,758	(23,181)
Cash and cash equivalents at the beginning of the period	39,572	63,663
Cash and cash equivalents at the end of the period	$44,330	$40,482

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

6

ORTHOFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

Business and basis of presentation

Orthofix International N.V. (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 has four strategic business units ("SBUs") that are also its reporting segments: BioStim, Biologics, Extremity Fixation, and Spine Fixation.

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 Form 10-K for the year ended December 31, 2016. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2017. The operating results for the three and six months ended June 30, 2016 have been adjusted from previously reported amounts as a result of the adoption of Accounting Standards Update ("ASU") 2016-09, which was adopted during the quarter ended September 30, 2016 with an effective date of January 1, 2016.

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 share-based compensation. Actual results could differ from these estimates.

1. Recently issued accounting pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Revenue Recognition (ASU 2014-09, as amended)	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. Applied either	January 1, 2018	The Company is continuing to evaluate the impact this ASU will have on its consolidated financial statements and disclosures. The Company completed an initial impact assessment and believes adopting this ASU will materially impact the timing of revenue recognition, primarily for Extremity Fixation and Spine Fixation product sales to stocking distributors, which are currently accounted for using the sell-through method.

	retrospectively or as a cumulative effect adjustment as of the adoption date.		Specifically, the Company believes the revenue associated with these sales will be recorded at the time of the sale instead of deferring recognition until cash is received. The Company expects to adopt this new guidance using the modified retrospective transition method.
Financial Instruments (ASU 2016-01) 7	Requires entities to measure equity investments, except in limited circumstances, at fair value and recognize any changes in fair value in net income. Applied prospectively.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Leases (ASU 2016-02)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach.	January 1, 2019	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will result in current operating lease obligations being reflected on the consolidated balance sheet.
Income Taxes (ASU 2016-16)	Reduces complexity by requiring current and deferred income taxes for intra-entity asset transfers, other than inventory, to be recognized when the transfer occurs. Applied using a modified retrospective approach.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
Statement of Cash Flows (ASU 2016-18)	Reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. Applied retrospectively.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated statement of cash flows.

2. Inventories

Inventories were as follows:

(U.S. Dollars, in thousands)	June 30, 2017	December 31, 2016
Raw materials	$5,049	$7,978
Work-in-process	11,339	9,505
Finished products	55,706	42,434
Deferred cost of sales	3,775	3,429
	$75,869	$63,346

3. Other current liabilities

In December 2016, the Company approved and initiated a planned restructuring, which primarily affects the Extremity Fixation SBU, to streamline costs, improve operational performance, and wind down a non-core business. The restructuring plan consists primarily of severance charges and the write-down of certain assets. The Company expects to incur total pre-tax expense of approximately $2.9 million in connection with this restructuring activity and has

incurred cumulative costs to date of $2.0 million. The Company had an accrual of $1.5 million as of December 31, 2016 in other current liabilities related to the planned restructuring. In the six months ended June 30, 2017, the Company increased its estimate of costs to be incurred by approximately $0.1 million and made additional payments of $0.6 million, resulting in an ending accrual of $1.0 million as of June 30, 2017.

4. Long-term debt

As of June 30, 2017, the Company has not made any borrowings under its five year $125 million secured revolving credit facility with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders party thereto. The Company has also not made any borrowings on its €5.8 million ($6.6 million) available line of credit in Italy at June 30, 2017. The Company is in compliance with all required financial covenants as of June 30, 2017.

5. Fair value measurements

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

	June 30, 2017				December 31, 2016
(U.S. Dollars, in thousands)	Level 1	Level 2	Level 3	Total	Total
Assets					
Collective trust funds	$—	$1,574	$—	$1,574	$ 1,584
Treasury securities	525	—	—	525	467
Certificates of deposit	—	—	—	—	468
Debt security	—	—	9,000	9,000	12,220
Total	$525	$1,574	$9,000	$11,099	$ 14,739
Liabilities					
Deferred compensation plan	$—	$(1,271)	$—	$(1,271)	$ (1,452)
Total	$—	$(1,271)	$—	$(1,271)	$ (1,452)

The fair value of the debt security, which is recorded within other long-term assets, is based upon significant unobservable inputs, including the use of a discounted cash flow model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. As of June 30, 2017, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of $9.0 million, which is consistent with the Company's estimated fair value from the first quarter of 2017. This compares to an amortized cost basis in the debt security of $18.0 million.

The Company evaluated the decline in fair value recorded during the first quarter of 2017 to determine if the impairment was other-than-temporary. Based on this evaluation, the Company recorded an other-than-temporary impairment charge of $5.6 million before income taxes, which is recorded in other expense. In addition to the decrease in fair value, the other-than-temporary impairment included a reclassification of the amount that was previously considered temporary and included in accumulated other comprehensive loss.

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)	2017	2016
Balance at January 1	$12,220	$12,658
Accrued interest income	—	640
Gains or losses recorded for the period		
Recognized in net income	(5,585)	—
Recognized in other comprehensive income	2,365	(3,860)
Balance at June 30	$9,000	$9,438

6. Contingencies

In addition to the matters described below, 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. The Company believes losses with respect to these additional matters are individually and collectively immaterial as to a possible loss and range of loss.

Discontinued Operations – Matters Related to Breg and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. (“Water Street”). Under the terms of the agreement, the Company indemnified 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.” One case remains outstanding for which the Company currently cannot reasonably estimate the possible loss, or range of loss.

- At the time of its divestiture by the Company, Breg was 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. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. Currently pending is a post-close cold therapy claim in California state court. As of June 30, 2017, the Company has an accrual of $2.6 million recorded within other current liabilities; however, the actual liability could be higher or lower than the amount accrued.

Charges incurred as a result of this indemnification are reflected as discontinued operations in the condensed consolidated statements of operations.

7. Accumulated other comprehensive loss

The components of and changes in accumulated other comprehensive loss were as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Debt Security	Accumulated Other Comprehensive Loss
Balance at December 31, 2016	$ (5,115)	$ (1,465)	$ (6,580)
Other comprehensive income (loss)	2,882	(3,220)	(338)
Income taxes	—	1,223	1,223
Reclassification adjustments to:			
Other expense, net	—	5,585	5,585
Income taxes	—	(2,123)	(2,123)
Balance at June 30, 2017	$ (2,233)	$ —	$ (2,233)

8. Revenue recognition

The table below presents net sales, which includes product sales and marketing service fees, for both the three and six months ended June 30, 2017 and 2016.

	Three Months Ended		Six Months Ended	
(U.S. Dollars, in thousands)	June 30, 2017	2016	June 30, 2017	2016
Product sales	$93,908	$90,868	$182,309	$176,493

Marketing service fees	15,034	13,207	29,371	26,261
Net sales	$108,942	$104,075	$211,680	$202,754

Product sales primarily consist of stimulation devices and fixation products. Marketing service fees are received from the Musculoskeletal Transplant Foundation (“MTF”) based on total sales of biologics tissues.

9. Business segment information

The table below present net sales, which includes product sales and marketing service fees, by reporting segment:

	Three Months Ended June 30,			
(U.S. Dollars, in thousands)	2017	2016	Change	
BioStim	$47,174	$44,758	5.4	%
Biologics	15,661	14,256	9.9	%
Extremity Fixation	24,747	26,817	-7.7	%
Spine Fixation	21,360	18,244	17.1	%
Net sales	$108,942	$104,075	4.7	%

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	Change
BioStim	$91,713	$85,802	6.9 %
Biologics	30,648	28,350	8.1 %
Extremity Fixation	48,692	51,526	-5.5 %
Spine Fixation	40,627	37,076	9.6 %
Net sales	$211,680	$202,754	4.4 %

The primary metric used in managing the Company is non-GAAP net margin, which is an internal metric that the Company defines as gross profit less sales and marketing expense. The table below presents non-GAAP net margin by reporting segment:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2017	2016	2017	2016
BioStim	$19,469	$18,575	$36,602	$34,983
Biologics	6,470	6,718	12,641	12,822
Extremity Fixation	6,766	8,161	13,178	15,336
Spine Fixation	2,696	2,201	4,703	4,536
Corporate	(107)	(139)	(205)	(441)
Non-GAAP net margin	$35,294	$35,516	$66,919	$67,236
General and administrative	20,409	18,545	38,691	35,550
Research and development	6,887	6,796	14,311	14,436
Charges related to U.S. Government resolutions	—	12,870	—	12,870
Operating income (loss)	$7,998	$(2,695)	$13,917	$4,380
Interest income (expense), net	76	(113)	121	(151)
Other income (expense), net	585	147	(3,763)	1,980
Income (loss) before income taxes	$8,659	$(2,661)	$10,275	$6,209

10. Share-based compensation

The following tables present the detail of share-based compensation by line item in the condensed consolidated statements of operations as well as by award type:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2017	2016	2017	2016
Cost of sales	$137	$109	$286	$226
Sales and marketing	319	280	679	556

General and administrative	2,005	1,376	4,107	2,934
Research and development	215	148	420	296
	$2,676	$1,913	$5,492	$4,012

	Three Months Ended		Six Months Ended	
(U.S. Dollars, in thousands)	June 30, 2017	2016	June 30, 2017	2016
Stock options	$523	$467	$1,118	$942
Time-based restricted stock awards	1,239	1,130	2,531	2,438
Performance-based restricted stock awards	113	—	225	—
Performance-based and market-based restricted stock units	472	—	938	—
Stock purchase plan	329	316	680	632
	$2,676	$1,913	$5,492	$4,012

During the three months ended June 30, 2017 and 2016, the Company issued 76,596 and 325,393 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards. During the six months ended June 30, 2017 and 2016, the Company issued 291,275 and 528,791 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

11. Income taxes

Income tax provisions for interim periods are based on an estimated annual income tax rate, adjusted for discrete tax items. As a result, the Company's interim effective tax rates may vary significantly from the statutory tax rate and the annual effective tax rate.

For the three months ended June 30, 2017 and 2016, the effective tax rate on continuing operations was 45.3% and (138.5%), respectively. For the six months ended June 30, 2017 and 2016, the effective tax rate on continuing operations was 76.4% and 128.5%.The primary factors affecting the Company's effective tax rate for the three and six months ended June 30, 2017, were the method for estimating income taxes at interim periods, the mix of earnings among tax jurisdictions and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

The Internal Revenue Service is currently conducting examinations of the Company's federal income tax returns for 2012 and 2013. The Company cannot reasonably determine if these examinations will have a material impact on its financial statements and cannot predict the timing regarding resolution of these tax examinations.

12. Earnings per share ("EPS")

For the three and six months ended June 30, 2017 and 2016, no adjustments were made to net income (loss) for purposes of calculating basic and diluted EPS. The following is a reconciliation of the weighted average shares used in diluted EPS computations.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Weighted average common shares-basic	18,050,551	18,147,681	18,015,308	18,312,781
Effect of dilutive securities				
Unexercised stock options and stock purchase plan	156,109	—	115,560	—
Unvested time-based restricted stock awards	136,378	—	157,182	—
Weighted average common shares-diluted	18,343,038	18,147,681	18,288,050	18,312,781

There were 462,146 and 532,277 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the three months ended June 30, 2017 and 2016, respectively, and 506,964 and 499,620 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the six months ended June 30, 2017 and 2016, respectively, because inclusion of these awards was anti-dilutive or, for performance-based and market-based awards, all necessary conditions had not been satisfied by the end of the respective period.

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

The following discussion and analysis of our financial condition and results of our operations should be read in conjunction with the "Forward-Looking Statements" and our condensed consolidated financial statements and related notes thereto appearing elsewhere in this Form 10-Q.

Executive Summary

Orthofix International N.V. (sometimes referred to as "we," "us" or "our") is 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, Texas, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Biologics, Extremity Fixation and Spine Fixation. Our products are widely distributed by our sales representatives and distributors.

Notable highlights and achievements in the second quarter of 2017 include the following:

- Net sales were $108.9 million, an increase of 4.7% on a reported basis and 5.1% on a constant currency basis
- Strong performance in our Biologics and Spine Fixation SBUs due to the renewed engagement of our sales partners, the addition of new distributors in underserved markets and our flow of new products to the field
- Operating income of $8.0 million, an increase of $10.7 million, compared to operating loss of $2.7 million in the prior year

Results of Operations

The following table provides certain items in our condensed consolidated statements of operations as a percent of net sales:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	21.3	21.6	21.6	22.0
Gross profit	78.7	78.4	78.4	78.0
Sales and marketing	46.3	44.2	46.8	44.8
General and administrative	18.7	17.8	18.3	17.5
Research and development	6.4	6.6	6.7	7.1
Charges related to U.S. Government resolutions	—	12.4	—	6.4
Operating income (loss)	7.3	(2.6)	6.6	2.2
Net income (loss) from continuing operations	4.3	(6.1)	1.1	(0.9)

Net Sales by Strategic Business Unit

The following tables provide net sales by SBU:

	Three Months Ended June 30,		Percentage Change	
(U.S. Dollars, in thousands)	2017	2016	Reported	Constant Currency
BioStim	$47,174	$44,758	5.4 %	5.4 %
Biologics	15,661	14,256	9.9 %	9.9 %
Extremity Fixation	24,747	26,817	-7.7 %	-6.0 %
Spine Fixation	21,360	18,244	17.1 %	17.1 %
Net sales	$108,942	$104,075	4.7 %	5.1 %

	Six Months Ended June 30,		Percentage Change	
(U.S. Dollars, in thousands)	2017	2016	Reported	Constant Currency
BioStim	$91,713	$85,802	6.9 %	6.9 %
Biologics	30,648	28,350	8.1 %	8.1 %
Extremity Fixation	48,692	51,526	-5.5%	-3.6 %
Spine Fixation	40,627	37,076	9.6 %	9.6 %
Net sales	$211,680	$202,754	4.4 %	4.9 %

BioStim

BioStim manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. BioStim uses distributors and sales representatives to sell its devices to hospitals, doctors, other healthcare providers, and patients.

Three months ended June 30, 2017 compared to 2016

Net sales increased $2.4 million, or 5.4%, as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society (“NASS”) coverage recommendation and the launch of our next generation products

Six months ended June 30, 2017 compared to 2016

Net sales increased $5.9 million, or 6.9%, as we continue to leverage the engagement of our expansive sales force, the positive NASS coverage recommendation and the launch of our next generation products

Biologics

Biologics provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. Biologics markets its tissues primarily in the U.S. through a network of distributors and independent sales representatives to supply to hospitals, doctors, and other healthcare providers.

Three months ended June 30, 2017 compared to 2016

Net sales increased $1.4 million or 9.9%

- Increase in volume for our Trinity products driven by the addition of new distributors over the past twelve months
- Benefit from improving performance from our national distribution partner and the reacquisition of a national hospital contract

Six months ended June 30, 2017 compared to 2016

Net sales increased $2.3 million or 8.1%

- Increase in volume for our Trinity products driven by the addition of new distributors over the past twelve months
- Benefit from improving performance from our national distribution partner and the reacquisition of a national hospital contract

Extremity Fixation

Extremity Fixation offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. Extremity Fixation distributes its products globally through a network of distributors and sales representatives to sell orthopedic products to hospitals, doctors, and other health providers.

Three months ended June 30, 2017 compared to 2016

Net sales decreased $2.0 million or 7.7%

- Decrease related to our international restructuring, which consists of the divestiture of a non-core business in the United Kingdom and a reduction in sales in Brazil and Puerto Rico as we convert from a direct sales model to the use of stocking distributors of $1.0 million
- Decrease as a result of changes in foreign currency exchange rates of $0.5 million
- Decrease in year-over-year cash collections for the quarter from international distributors whose revenue is recognized upon cash receipt
- Partially offset by growth in the U.S., largely due to the continued adoption of our TL-HEX product line

Six months ended June 30, 2017 compared to 2016

Net sales decreased $2.8 million or 5.5%

- Decrease related to our international restructuring, which consists of the divestiture of a non-core business in the United Kingdom and a reduction in sales in Brazil and Puerto Rico as we convert from a direct sales model to the use of stocking distributors of $1.5 million
- Decrease as a result of changes in foreign currency exchange rates of $1.0 million
- Decrease in year-over-year cash collections for the quarter from international distributors whose revenue is recognized upon cash receipt
- Partially offset by growth in the U.S., largely due to the continued adoption of our TL-HEX product line

Spine Fixation

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

Three months ended June 30, 2017 compared to 2016

Net sales increased $3.1 million or 17.1%

- Increase in U.S. sales due to the addition of new distributor partners in the last several quarters, the uptake of recent product introductions, and improved distributor engagement
- Partially offset by a decrease in year-over-year international sales, largely due to a decrease in cash collections for the quarter from international distributors whose revenue is recognized upon cash receipt

Six months ended June 30, 2017 compared to 2016

Net sales increased $3.6 million or 9.6%

- Increase in U.S. sales due to the addition of new distributor partners in the last several quarters, the uptake of recent product introductions, and improved distributor engagement
- Partially offset by a decrease in year-over-year international sales, largely due to a decrease in cash collections for the quarter from international distributors whose revenue is recognized upon cash receipt

Gross Profit and Non-GAAP Net Margin

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
Gross profit	$85,765	$81,559	5.2 %	$165,922	$158,101	4.9 %
Sales and marketing	(50,471)	(46,043)	9.6 %	(99,003)	(90,865)	9.0 %
Non-GAAP net margin	$35,294	$35,516	-0.6 %	$66,919	$67,236	-0.5 %
Gross margin	78.7 %	78.4 %	0.3 %	78.4 %	78.0 %	0.4 %
Non-GAAP net margin as a percentage of net sales	32.4 %	34.1 %	-1.7 %	31.6 %	33.2 %	-1.6 %

Three months ended June 30, 2017 compared to 2016

Gross profit, sales and marketing expense, and non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense changed as follows:

- Gross profit increased $4.2 million, primarily due to the growth in net sales
- Sales and marketing expense increased $4.4 million, primarily due to a higher mix of sales from new distributors in Biologics, who typically receive higher commissions in their first year, and higher spending in Extremity Fixation related to our sales growth in the U.S.
- Non-GAAP net margin decreased by $0.2 million as a result of the changes in gross profit and sales and marketing expense

Six months ended June 30, 2017 compared to 2016

Gross profit, sales and marketing expense, and non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense changed as follows:

- Gross profit increased $7.8 million, primarily due to the growth in net sales
- Sales and marketing expense increased $8.1 million, primarily due to a higher mix of sales from new distributors in Biologics and Spine Fixation, who typically receive higher commissions in their first year, and higher spending in Extremity Fixation related to our sales growth in the U.S.
- Non-GAAP net margin decreased by $0.3 million as a result of the changes in gross profit and sales and marketing expense

The following table provides non-GAAP net margin by SBU. The reasons for the changes in non-GAAP net margin by SBU are generally consistent with the information provided above for gross profit and sales and marketing expense.

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
BioStim	$19,469	$18,575	4.8 %	$36,602	$34,983	4.6 %
Biologics	6,470	6,718	-3.7 %	12,641	12,822	-1.4 %
Extremity Fixation	6,766	8,161	-17.1 %	13,178	15,336	-14.1 %
Spine Fixation	2,696	2,201	22.5 %	4,703	4,536	3.7 %
Corporate	(107)	(139)	-23.0 %	(205)	(441)	-53.5 %
Non-GAAP net margin	$35,294	$35,516	-0.6 %	$66,919	$67,236	-0.5 %

General and Administrative Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
General and administrative	$20,409	$18,545	10.1 %	$38,691	$35,550	8.8 %
As a percentage of net sales	18.7 %	17.8 %	0.9 %	18.3 %	17.5 %	0.8 %

Three months ended June 30, 2017 compared to 2016

General and administrative expense increased $1.9 million

- Increase in spending related to strategic initiatives of $2.0 million and legal settlements of $1.4 million
- Increase in share-based compensation expense of $0.6 million related to performance-based and market-based awards
- Partially offset by a reduction in Project Bluecore expenses of $1.3 million as the project was completed in 2016
- Further offset by $1.0 million in cost containment in professional fees within our finance and legal departments

Six months ended June 30, 2017 compared to 2016

General and administrative expense increased $3.1 million

- Increase in spending related to strategic initiatives of $3.3 million and legal settlements of $1.6 million
- Increase in share-based compensation expense of $1.2 million related to performance-based and market-based awards
- Partially offset by a reduction in Project Bluecore expenses of $2.2 million as the project was completed in 2016

- Further offset by $0.5 million cost containment in professional fees within our finance and legal departments

Research and Development Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
Research and development	$6,887	$6,796	1.3 %	$14,311	$14,436	-0.9 %
As a percentage of net sales	6.4 %	6.6 %	-0.2 %	6.7 %	7.1 %	-0.4 %

Three months ended June 30, 2017 compared to 2016

Research and development expense increased by less than $0.1 million compared to the prior year

Six months ended June 30, 2017 compared to 2016

Research and development expense decreased by $0.1 million compared to the prior year

Charges Related to U.S. Government Resolutions

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
Charges related to U.S. Government resolutions	$—	$12,870	-100.0 %	$—	$12,870	-100.0 %
As a percentage of net sales	0.0%	12.4 %	-12.4 %	0.0%	6.4 %	-6.4 %

Three and Six months ended June 30, 2017 compared to 2016

Decrease of $12.9 million related to charges for settlements with the Division of Enforcement of the SEC in 2016 related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil. For additional information, see Note 12 within our Form 10-K for the year ended December 31, 2016.

Non-operating Income and Expense

In the first quarter of 2017, we recorded an other-than-temporary impairment on the eNeura debt security of $5.6 million before income taxes. For additional discussion see Note 5 to the Notes to the Unaudited Condensed Consolidated Financial Statements.

Income Taxes

	Three Months Ended June 30,	Six Months Ended June 30,

(U.S. Dollars, in thousands)	2017	2016	% Change	2017	2016	% Change
Income tax expense	$3,924	$3,685	6.5 %	$7,848	$7,979	-1.6 %
Effective tax rate	45.3 %	-138.5%	183.8 %	76.4 %	128.5%	-52.1 %

Three months ended June 30, 2017 compared to 2016

The increase in the effective tax rate is due to charges related to U.S. Government resolutions which were non-deductible for tax purposes and did not recur in 2017. The primary factors affecting our effective tax rate for the second quarter of 2017 are as follows:

- The mix of earnings among tax jurisdictions
- Current period losses in jurisdictions where we do not currently receive a tax benefit

Six months ended June 30, 2017 compared to 2016

The decrease in the effective tax rate was primarily a result of the following factors:

- Charges related to U.S. Government resolutions in 2016, which were non-deductible for tax purposes, that did not recur in 2017
- Partially offset by the other-than-temporary impairment on the eNeura debt security in the first quarter of 2017

The primary factors affecting our effective tax rate for the six months ended June 30, 2017 are as follows:

- The mix of earnings among tax jurisdictions
- Current period losses in jurisdictions where we do not currently receive a tax benefit

Liquidity and Capital Resources

Cash and cash equivalents at June 30, 2017, were $44.3 million compared to $39.6 million at December 31, 2016.

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	Change
Net cash from operating activities	$9,727	$21,373	$(11,646)
Net cash from investing activities	(8,119)	(13,969)	5,850
Net cash from financing activities	2,431	(30,850)	33,281
Effect of exchange rate changes on cash	719	265	454
Net change in cash and cash equivalents	$4,758	$(23,181)	$27,939

The following table presents free cash flow, a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities.

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2017	2016	Change
Net cash from operating activities	$9,727	$21,373	$(11,646)
Capital expenditures	(8,593)	(10,356)	1,763
Free cash flow	$1,134	$11,017	$(9,883)

Operating Activities

Cash flows from operating activities decreased $11.6 million

- Increase in net income of $4.8 million
- Net increase of $10.6 million for non-cash gains and losses, largely related to the other-than-temporary impairment on the eNeura debt security in the first quarter of 2017, deferred income tax expense, and share-based compensation expense
- Net decrease of $27.0 million relating to changes in working capital accounts, primarily attributable to changes in other current liabilities as a result of U.S. Government resolutions (discussed in further detail below), an increase in our inventory balance as a result of new product introductions, and accounts receivable as a result of the increase in net sales

Our two primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 51 days at June 30, 2017 compared to 49 days at June 30, 2016. Inventory turns were 1.2 times as of June 30, 2017 compared to 1.5 times at June 30, 2016. The decline in inventory turns reflects the new product introductions in our Spine Fixation and Extremity Fixation SBUs.

U.S. Government Resolutions

In January 2017, the U.S. Securities and Exchange Commission (the “SEC”) approved our offers of settlement in connection with the SEC’s investigations of accounting matters leading to our prior restatement of financial statements and our review of improper payments in Brazil. The settlements approved by the SEC resolved these two matters, and included payments to the SEC of amounts previously accrued and funded into escrow during 2016.

Investing Activities

Cash flows from investing activities increased $5.9 million

- Increase of $3.6 million from the purchase of certain inventory and intellectual property assets of $2.6 million and our additional investment in Bone Biologics, Inc. of $1.0 million during 2016
- Increase of $1.8 million related to reduced capital expenditures, largely as a result of completing Project Bluecore in 2016

Financing Activities

Cash flows from financing activities increased $33.3 million

- Increase of $43.9 million related to the share repurchase plan, which was completed in 2016
- Partially offset by a decrease in net proceeds of $10.6 million from the issuance of common shares

Credit Facilities

There have been no material changes to our debt instruments as disclosed in our Form 10-K for the year ended December 31, 2016.

Other

For information regarding Contingencies, see Note 6 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of June 30, 2017, 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 Form 10-K for the year ended December 31, 2016.

Critical Accounting Estimates

There have been no material changes to our critical accounting estimates, as described in our Form 10-K for the year ended December 31, 2016.

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.

Non-GAAP Financial Measures

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater transparency to the information used by senior management in its financial and operational decision-making. We believe it is important to provide investors with the same non-GAAP metrics used to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to

historical operating results and internally evaluate the effectiveness of the our operating strategies. Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial measures.

The non-GAAP financial measures used in this filing may have limitations as analytical tools, and should not be considered in isolation or as a replacement for GAAP financial measures. Some of the limitations associated with the use of these non-GAAP financial measures are that they exclude items that reflect an economic cost that can have a material effect on cash flows.

Constant Currency

Constant currency is calculated by using foreign currency rates from the comparable, prior-year period, to present net sales at comparable rates. Constant currency can be presented for numerous GAAP measures, but is most commonly used by management to analyze net sales without the impact of changes in foreign currency rates.

Non-GAAP Net Margin

Non-GAAP net margin is an internal metric that we define as gross profit less sales and marketing expense. Non-GAAP net margin is the primary metric used by our Chief Operating Decision Maker in managing the business.

Free Cash Flow

Free cash flow is calculated by subtracting capital expenditures from net cash from operating activities. Free cash flow is an important indicator of how much cash is generated or used by our normal business operations, including capital expenditures. Management uses free cash flow as a measure of progress on its capital efficiency and cash flow initiatives.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes to our market risks as disclosed in our Form 10-K for the year ended December 31, 2016.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that the information required to be disclosed in reports filed or submitted under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. These include controls and procedures designed to ensure that this information is accumulated and communicated to management, including our President and Chief Executive Officer and our 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 our disclosure controls and procedures as of June 30, 2017. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that the disclosure controls and procedures were effective as of June 30, 2017.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, see Note 6 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 to the risk factors disclosed in the “Risk Factors” section of our Form 10-K for the year ended December 31, 2016.

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

We have not made any repurchases of our common stock during the second quarter of 2017.

Item 3. Defaults Upon Senior Securities

Not applicable.

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*	Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan
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 7, 2017 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: August 7, 2017 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer