Orthofix Medical Inc.
Form 10-Q
August 06, 2018

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, 2018

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 MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware	98-1340767
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3451 Plano Parkway,	
Lewisville, Texas	75056
(Address of principal executive offices)	(Zip Code)

(214) 937-2000

(Registrant's telephone number, including area code)

Orthofix International N.V.

7 Abraham de Veerstraat

Curaçao

(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 3, 2018, 18,910,949 shares of common stock were issued and outstanding.

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Explanatory Note

On July 31, 2018, Orthofix Medical Inc. (previously Orthofix International N.V.) (the "Company," "we," "us" and "our") completed a change in its jurisdiction of organization from Curaçao to the State of Delaware (the "domestication") in accordance with the conversion procedures of the Curaçao Civil Code and the domestication procedures of Delaware General Corporation Law. In connection with the domestication, the Company changed its name to "Orthofix Medical Inc." The Company's shareholders approved a proposal to adopt a shareholders' resolution authorizing the domestication at the Company's 2018 Annual General Meeting of Shareholders held on July 17, 2018.

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 , including the risks described Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "2017 Form 10-K") and other SEC filings. 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 the 2017 Form 10-K and other SEC filings, 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 MEDICAL INC.

Condensed Consolidated Balance Sheets

(U.S. Dollars, in thousands, except share data)	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 45,686	$ 81,157
Accounts receivable, net of allowances of $8,490 and $8,405, respectively	74,397	63,437
Inventories	81,730	81,330
Prepaid expenses and other current assets	35,613	25,877
Total current assets	237,426	251,801
Property, plant and equipment, net	44,377	45,139
Intangible assets, net	51,498	10,461
Goodwill	70,747	53,565
Deferred income taxes	30,634	23,315
Other long-term assets	7,082	21,073
Total assets	$ 441,764	$ 405,354
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 14,453	$ 18,111
Other current liabilities	49,486	61,295
Total current liabilities	63,939	79,406
Other long-term liabilities	57,979	29,340
Total liabilities	121,918	108,746
Contingencies (Note 6)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,485,788 and 18,278,833 issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	1,849	1,828
Additional paid-in capital	233,742	220,591
Retained earnings	79,418	70,402
Accumulated other comprehensive income	4,837	3,787
Total shareholders' equity	319,846	296,608
Total liabilities and shareholders' equity	$ 441,764	$ 405,354

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

ORTHOFIX MEDICAL INC.

Condensed Consolidated Statements of Income and Comprehensive Income

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Net sales	$111,547	$108,942	$220,256	$211,680
Cost of sales	22,835	23,177	46,982	45,758
Gross profit	88,712	85,765	173,274	165,922
Sales and marketing	51,529	50,471	101,797	99,003
General and administrative	22,268	20,409	41,752	38,691
Research and development	7,891	6,887	14,828	14,311
Operating income	7,024	7,998	14,897	13,917
Interest income (expense), net	(251)	76	(434)	121
Other income (expense), net	(4,752)	585	(1,840)	(3,763)
Income before income taxes	2,021	8,659	12,623	10,275
Income tax expense	(1,088)	(3,924)	(6,461)	(7,848)
Net income from continuing operations	933	4,735	6,162	2,427
Discontinued operations (Note 6)				
Loss from discontinued operations	—	(1,300)	(3)	(1,827)
Income tax benefit (expense)	(8)	418	(8)	599
Net loss from discontinued operations	(8)	(882)	(11)	(1,228)
Net income	$925	$3,853	$6,151	$1,199
Net income (loss) per common share—basic				
Net income from continuing operations	$0.05	$0.26	$0.33	$0.13
Net loss from discontinued operations	—	(0.05)	—	(0.06)
Net income per common share—basic	$0.05	$0.21	$0.33	$0.07
Net income (loss) per common share—diluted				
Net income from continuing operations	$0.05	$0.26	$0.32	$0.13
Net loss from discontinued operations	—	(0.05)	—	(0.06)
Net income per common share—diluted	$0.05	$0.21	$0.32	$0.07
Weighted average number of common shares:				
Basic	18,413,756	18,050,551	18,409,331	18,015,308
Diluted	18,835,560	18,343,038	18,811,356	18,288,050
Other comprehensive income, before tax				
Unrealized gain (loss) on debt securities	1,960	—	1,960	(3,220)
Reclassification adjustment for loss on debt securities in net income	—	—	—	5,585
Currency translation adjustment	(1,175)	2,648	(478)	2,882
Other comprehensive income before tax	785	2,648	1,482	5,247
Income tax related to items of other comprehensive income	(432)	—	(432)	(900)
Other comprehensive income, net of tax	353	2,648	1,050	4,347

Comprehensive income	$1,278	$6,501	$7,201	$5,546

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

ORTHOFIX MEDICAL INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited, U.S. Dollars, in thousands)	Six Months Ended June 30, 2018	2017
Cash flows from operating activities		
Net income	$6,151	$1,199
Adjustments to reconcile net income to net cash from operating activities		
Depreciation and amortization	8,923	10,447
Amortization of debt costs and other assets	592	719
Provision for doubtful accounts	(360)	820
Deferred income taxes	724	4,284
Share-based compensation	9,131	5,492
Other-than-temporary impairment on debt securities	—	5,585
Gain on valuation of equity securities	(1,399)	—
Revaluation of contingent consideration	1,109	—
Other	847	572
Changes in operating assets and liabilities, net of effects of acquisition		
Accounts receivable	(363)	(3,787)
Inventories	5,251	(11,119)
Prepaid expenses and other current assets	71	2,199
Accounts payable	(3,847)	(950)
Other current liabilities	(14,612)	(19,407)
Other long-term assets and liabilities	814	(696)
Net cash from operating activities	13,032	(4,642)
Cash flows from investing activities		
Acquisition of business, net of cash acquired	(43,749)	—
Capital expenditures for property, plant and equipment	(5,782)	(7,035)
Capital expenditures for intangible assets	(870)	(1,558)
Asset acquisition and other investments	(1,148)	—
Other investing activities	—	474
Net cash from investing activities	(51,549)	(8,119)
Cash flows from financing activities		
Proceeds from issuance of common shares	5,416	5,282
Payments related to withholdings for share-based compensation	(1,375)	(2,851)
Payment of debt issuance costs and other financing activities	(356)	—
Net cash from financing activities	3,685	2,431
Effect of exchange rate changes on cash	(639)	719
Net change in cash, cash equivalents, and restricted cash	(35,471)	(9,611)
Cash, cash equivalents, and restricted cash at the beginning of the period	81,157	53,941
Cash, cash equivalents, and restricted cash at the end of the period	$45,686	$44,330
Supplemental Disclosure of Cash Flow Information:		
Noncash investing activities:		

Purchase of intangible assets	1,181	—
Contingent consideration recognized at acquisition date	25,491	—

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

ORTHOFIX MEDICAL INC.

Notes to the Unaudited Condensed Consolidated Financial Statements

Business and basis of presentation

Orthofix Medical Inc. (previously Orthofix International N.V.), together with its subsidiaries (the “Company” or “Orthofix”) is a global medical device company focused on musculoskeletal products and therapies. Headquartered in Lewisville, Texas, the Company has four strategic business units (“SBUs”) that are also its reporting segments: BioStim, Spine Fixation, Biologics, and Extremity 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, 2017. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2018.

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, 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 adopted accounting standards and recently issued accounting pronouncements

Adoption of accounting standards update (“ASU”) 2014-09, Revenue from Contracts with Customers (Topic 606)

In May 2014, the FASB issued ASU 2014-09. Topic 606 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective transition method. Results for prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under the previous revenue recognition standard, Topic 605. See Note 8 for further details.

Adoption of ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10), and ASU 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10)

In January 2016, the FASB issued ASU 2016-01, which was then further clarified in ASU 2018-03, in February 2018. This guidance requires entities to generally measure equity investments at fair value and recognize any changes in fair value in net income. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows entities to choose to measure these investments using a new measurement alternative, which values the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. The Company prospectively adopted both ASU 2016-01 and ASU 2018-03 on January 1, 2018 and elected to use the new measurement alternative for the Company's equity investments in Bone Biologics, Inc. ("Bone Biologics"), which have historically been held at cost. This resulted in an increase in the previously recorded value of the Company's equity investments in Bone Biologics, which are recorded within other current assets or long term assets, of $1.6 million, or $0.09 per share before taxes, during the three months ended March 31, 2018, which is included in other income (expense). See Note 5 for further details.

Adoption of ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory

In October 2016, the FASB issued ASU 2016-16, which reduces diversity in practice of accounting for intra-entity transfers of assets, particularly for intra-entity transfers of intellectual property. The new standard states an entity should recognize the income tax consequences of an intra-entity transfer when the transfer occurs, as opposed to historical U.S. GAAP guidance which prohibited the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset had been sold to an outside party. During the third and fourth quarters of 2017, the Company executed two intra-entity asset transfers that resulted in prepaid income

taxes of $8.6 million. The Company adopted this new standard using a modified retrospective approach as of January 1, 2018, which resulted in a reduction of prepaid income taxes and an increase in deferred tax assets with these changes offset by an adjustment to the Company's opening retained earnings of approximately $1.9 million. Adoption of this guidance did not have a material impact to the Company’s condensed consolidated statements of income and comprehensive income or to its condensed consolidated statements of cash flows.

Adoption of ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash

In November 2016, the FASB issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. The Company adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in a decrease in net cash from operating activities of $14.4 million for the six months ended June 30, 2017.

Adoption of ASU 2017-01, Business Combinations (Topic 805)

In January 2017, the FASB issued ASU 2017-01, which clarifies the definition of a business. This amendment states that when substantially all of the fair value of gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, that the set of assets acquired is not a business, which will likely result in more acquisitions being accounted for as asset acquisitions rather than business combinations. Based upon this guidance, which the Company adopted as of January 1, 2018, the Company accounted for an acquisition during the first quarter of 2018 for approximately $1.9 million as an asset acquisition rather than a business combination, as the set of assets acquired did not meet the definition of a business.

Recently issued accounting pronouncements

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 has established a cross-functional implementation team to analyze the impact of the standard on the Company's population of leases and to evaluate the Company's current accounting policies relating to leases. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will materially impact the Company's consolidated balance sheet, resulting in current operating lease obligations being reflected on the consolidated balance sheet.
Goodwill (ASU 2017-04)	Eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment loss will instead be measured at the amount by which a reporting unit's carrying value exceeds its fair value,	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements. However, the Company does not expect this ASU to have a significant impact on its financial statements or disclosures.

	not to exceed the recorded amount of goodwill. Applied on a prospective basis, with early adoption permitted.		
Comprehensive income (ASU 2018-02)	Allows entities to reclassify from accumulated other comprehensive income to retained earnings stranded tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act"). Applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Act is recognized.	January 1, 2019	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

2. Acquisition of Spinal Kinetics, Inc.

On March 15, 2018, the Company entered into a definitive merger agreement (the "Merger Agreement") to acquire 100% of the outstanding stock of Spinal Kinetics Inc. ("Spinal Kinetics"), a privately held developer and manufacturer of artificial cervical and lumbar discs, to strengthen the Company's product portfolio and fill a strategic gap in the Spine Fixation business. On April 30, 2018, the Company completed the acquisition and all outstanding shares of Spinal Kinetics' capital stock were converted into the right to receive at the closing an aggregate of $45.0 million in net cash, subject to certain adjustments, plus potential milestone payments of up to $60.0 million in cash. The Company made the closing payments from cash on hand on April 30, 2018. The results of operations for Spinal Kinetics have been included in the Company's financial results since the acquisition date, April 30, 2018.

The acquisition date fair value of the consideration transferred was $76.1 million, which consisted of the following:

(U.S. Dollars, in thousands)	
Fair value of consideration transferred	
Cash paid	50,564
Contingent consideration	25,491
Total fair value of consideration transferred	76,055

The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash. The milestone payments include (i) up to $15.0 million if the U.S. Food and Drug Administration grants approval of Spinal Kinetics' M6-C artificial disc ("the FDA Milestone") and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. Milestones must be achieved within five years of April 30, 2018 to trigger applicable payments. The fair value of the contingent consideration arrangement at the acquisition date was $25.5 million and was $26.6 million as of June 30, 2018; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. The increase in fair value of $1.1 million was recorded in other expense. For additional discussion regarding the valuation of the contingent consideration, see Note 5.

The following table summarizes the preliminary estimated fair values of the assets acquired and liabilities assumed at the acquisition date. A final determination of the allocation of the purchase price to assets acquired and liabilities assumed has not been made and the following should be considered preliminary. The final determination is subject to completion of the Company's valuation of the assets acquired and liabilities assumed, which it expects to complete within one year.

(U.S. Dollars, in thousands)	As of April 30, 2018	Assigned Useful Life
Assets acquired		
Cash and cash equivalents	$6,785	
Restricted cash	30	
Accounts receivable	1,705	
Inventories	8,175	

Prepaid expenses and other current assets	315	
Property, plant and equipment	2,285	
Other long-term assets	320	
Developed technology	12,400	10 years
In-process research and development ("IPR&D")	26,800	Indefinite
Tradename	100	2 years
Deferred income taxes	3,483	
Total identifiable assets acquired	62,398	
Liabilities assumed		
Accounts payable	$351	
Other current liabilities	2,873	
Other long-term liabilities	301	
Total liabilities assumed	3,525	
Goodwill	17,182	
Total fair value of consideration transferred	76,055	

The purchase price exceeded the fair value of the net tangible and identifiable intangible assets acquired from Spinal Kinetics. As a result, the Company recorded goodwill in connection with the acquisition. Specifically, the goodwill includes the assembled workforce and synergies associated with the combined entity. The goodwill is not expected to be deductible for tax purposes. The $17.2 million of goodwill recognized was assigned to the Spine Fixation reporting segment.

The IPR&D intangible asset is considered an indefinite-lived asset until the completion or abandonment of the associated research and development efforts. Accordingly, during the development period after the acquisition, this asset is not amortized but, instead, is subject to impairment review and testing provisions. Upon completion of the IPR&D project, the Company will determine the useful life of the asset and begin amortization.

The Company recognized $1.5 million and $3.0 million of acquisition related costs that were expensed during the three and six months ended June 30, 2018, respectively. These costs are included in the condensed consolidated statements of income and comprehensive income within general and administrative expenses. The Company's results of operations included $2.3 million of revenue from Spinal Kinetics from the date of acquisition for the three and six months ended June 30, 2018 and net loss of $1.8 million from the date of acquisition for the three and six months ended June 30, 2018 in the condensed consolidated statement of income and comprehensive income.

The following table presents the unaudited pro forma results for the six months ended June 30, 2018 and 2017, which combines the historical results of operations of Orthofix and Spinal Kinetics as though the companies had been combined as of January 1, 2017. The unaudited pro forma information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at such time.

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2018	2017	Six Months Ended June 30, 2018	2017
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net sales	$112,718	$ 112,350	$225,173	$ 219,163
Net income (loss) from continuing operations	2,161	2,484	7,099	(1,076)

3. Inventories

Inventories were as follows:

(U.S. Dollars, in thousands)	June 30, 2018	December 31, 2017
Raw materials	$9,210	$ 6,067
Work-in-process	13,502	12,487
Finished products	59,018	60,441

Deferred cost of sales	—	2,335
Inventories	$81,730	$ 81,330

Prior to the adoption of ASU 2014-09, or for all periods presented prior to January 1, 2018, deferred cost of sales resulted from certain transactions where the Company had shipped product or performed services for which all revenue recognition criteria had not yet been met. Once all revenue recognition criteria had been met, the revenue and associated cost of sales were recognized. Subsequent to the adoption of ASU 2014-09, the Company no longer has transactions which result in the recognition of deferred cost of sales. See Note 8 for further discussion of the Company’s adoption of ASU 2014-09.

4. Long-term debt

As of June 30, 2018, the Company has no borrowings under the five year $125 million secured revolving credit facility it entered into in August 2015 with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders. In addition, the Company has no borrowings on its €5.8 million ($6.8 million) available line of credit in Italy as of June 30, 2018. The Company is in compliance with all required financial covenants as of June 30, 2018.

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, 2018 Level 1	Level 2	Level 3	Total	December 31, 2017 Total
Assets					
Collective trust funds	$—	$100	$—	$100	$ 100
Treasury securities	558	—	—	558	556
Equity warrants	—	289	—	289	311
Equity securities	—	4,379	—	4,379	2,457
Debt security	—	—	18,010	18,010	16,050
Total	$558	$4,768	$18,010	$23,336	$ 19,474
Liabilities					
Contingent consideration	$—	$—	$(26,600)	$(26,600)	$ —
Deferred compensation plan	—	(1,369)	—	(1,369)	(1,379)
Total	$—	$(1,369)	$(26,600)	$(27,969)	$ (1,379)

Equity Warrants and Securities

The Company holds investments in common stock and warrants to purchase shares of common stock of Bone Biologics, Inc. ("Bone Biologics"). The Company's common stock investments are recorded within other long-term assets while the warrants are recorded within other current assets or other long-term assets, dependent upon the expiration date. Prior to 2018, these instruments were accounted for at cost as the fair value of these instruments was not readily determinable. Effective January 1, 2018, the Company is required to measure these equity investments at fair value and recognize any changes in fair value in net income as a result of adopting ASU 2016-01. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows entities to choose to measure these investments using a new measurement alternative, which values the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. The Company has elected to use the new measurement alternative for these equity investments in Bone Biologics, which resulted in an increase in the previously recorded value of the equity investments of $1.6 million, or $0.09 per share before taxes, during the three months ended March 31, 2018. These changes are classified as other income or expense. In addition, the Company made an additional investment in Bone Biologics during the first quarter of 2018, in which it purchased an additional 250,000 shares of common stock for $0.5 million.

Debt Security

The Company holds a debt security of eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The debt security matures on March 4, 2019. The fair value of the debt security, which is recorded within other current 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, 2018, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of $18.0 million, an increase of $2.0 million when compared to the Company's estimated fair value of the debt security as of December 31, 2017. This compares to an amortized cost basis in the debt security of $9.0 million.

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)	2018	2017
Debt security at January 1	$16,050	$12,220
Accrued interest income	—	—
Gains or losses recorded for the period		
Recognized in net income	—	(5,585)
Recognized in other comprehensive income	1,960	2,365
Debt security at June 30	$18,010	$9,000

Contingent Consideration

The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition. The milestone payments include (i) up to $15.0 million if the U.S. Food and Drug Administration grants approval of Spinal Kinetics' M6-C artificial disc ("the FDA Milestone") and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. Milestones must be achieved within five years of April 30, 2018 to trigger applicable payments. The fair value of the contingent consideration arrangement at the acquisition date was $25.5 million and was $26.6 million as of June 30, 2018; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. The increase in fair value of $1.1 million was recorded in other expense.

The Company estimated the fair value of the contingent consideration attributable to the FDA Milestone using a probability-weighted discounted cash flow model. This fair value is based on significant inputs not observable in the market and thus represents a Level 3 measurement. The key assumptions in applying the probability-weighted discounted cash flow model include the Company's estimation of the probability and timing of obtaining FDA approval for the M6-C artificial disc. Significant changes in these assumptions could result in a significantly higher or lower fair value.

The Company estimated the fair value of the potential future revenue-based milestone payments using a Monte Carlo simulation. This fair value measurement is based on significant inputs that are unobservable in the market, and thus represents a Level 3 measurement. The key assumptions in applying the Monte Carlo valuation model include the Company's forecasted future revenues for Spinal Kinetics products, discount rate applied, and assumptions for potential volatility of the Company's forecasted revenue. Significant changes in these assumptions could result in a significantly higher or lower fair value.

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

(U.S. Dollars, in thousands)	2018
Contingent consideration at January 1	$—
Acquisition date fair value	25,491
Increase in fair value recognized in other income (expense)	1,109
Contingent consideration at June 30	$26,600

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 any losses related to these 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.

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 were filed, mostly in California state court. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. In May 2018, Breg settled and resolved a post-close cold therapy claim in California state court, Gmeiner v. Breg, Inc. Pursuant to Orthofix's indemnification obligations to Breg, Orthofix was obligated to make a final payment to its insurer, Berkley Life Sciences, in the amount of $1.7 million, which was the remaining balance on Orthofix's Self-Insured Retention in its liability insurance policy, to help fund the Breg settlement in the Gmeiner matter.

Charges incurred as a result of this indemnification obligation to Breg are reflected as discontinued operations in the condensed consolidated statements of income and comprehensive income.

Italian Medical Device Payback ("IMDP")

In 2015, the Italian Parliament introduced rules for entities that supply goods and services to the Italian National Healthcare System. The healthcare law is expected to impact the business and financial reporting of companies operating in the medical technology

sector that sell medical devices in Italy. A key provision of the law is a ‘payback’ measure, requiring companies selling medical devices in Italy to make payments to the Italian government if medical device expenditures exceed regional maximum ceilings. Companies are required to make payments equal to a percentage of expenditures exceeding maximum regional caps. There is considerable uncertainty about how the law will operate and what the exact timeline is for finalization. The Company’s current assessment of the IMDP involves significant judgment regarding the expected scope and actual implementation terms of the measure as the latter have not been clarified to date by Italian authorities. The Company accounts for the estimated cost of the IMDP as sales and marketing expense and as of June 30, 2018, the Company has accrued €2.8 million ($3.3 million) related to the IMDP; however, the actual liability could be higher or lower than the amount accrued once the law has been clarified by the Italian authorities.

7. Accumulated other comprehensive income

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

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Debt Security	Accumulated Other Comprehensive Income
Balance at December 31, 2017	$ (563)	$ 4,350	$ 3,787
Other comprehensive income	(478)	1,960	1,482
Income taxes	—	(432)	(432)
Balance at June 30, 2018	$ (1,041)	$ 5,878	$ 4,837

8. Revenue recognition and accounts receivable

Adoption of ASU 2014-09, “Revenue from Contracts with Customers”

Effective January 1, 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606) using the modified retrospective transition method, which was applied to all contracts. Results for the three and six months ended June 30, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under the previous revenue recognition standard, Topic 605.

The Company recorded a net increase to opening retained earnings of $4.8 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606 as presented in the table below.

(U.S. Dollars, in thousands)	December 31, 2017	Impact of Adoption of ASC 606	January 1, 2018
Assets			
Current assets			
Cash and cash equivalents	$81,157	$ —	$81,157
Accounts receivable, net	63,437	8,648	72,085
Inventories	81,330	(2,338)	78,992
Prepaid expenses and other current assets	25,877	—	25,877
Total current assets	251,801	6,310	258,111
Deferred income taxes	23,315	(1,549)	21,766
Other long-term assets	130,238	—	130,238
Total assets	$405,354	$ 4,761	$410,115
Liabilities and shareholders' equity			
Total liabilities	108,746	—	108,746
Shareholders' equity			
Common shares	1,828	—	1,828
Additional paid-in capital	220,591	—	220,591
Retained earnings	70,402	4,761	75,163
Accumulated other comprehensive income	3,787	—	3,787
Total shareholders' equity	296,608	4,761	301,369
Total liabilities and shareholders' equity	$405,354	$ 4,761	$410,115

The impact primarily related to an increase in trade accounts receivable, net, from the Company's stocking distributors, for which revenue was historically recognized when cash payment was received, and the recognition of previously deferred cost of sales for certain stocking distributor transactions, which were historically included within inventory. Adoption of Topic 606 had no impact to cash from or used in operating, investing, or financing activities on the condensed consolidated statement of cash flows.

The table below presents the impact to the Company's condensed consolidated statement of income for the three and six months ended June 30, 2018 as a result of the adoption of Topic 606.

	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
(U.S. Dollars, in thousands)	Based on historical accounting under Topic 605	Impact of adoption	As reported under Topic 606	Based on historical accounting under Topic 605	Impact of adoption	As reported under Topic 606
Net sales	$113,400	$(1,853)	$111,547	$214,762	$ 5,494	$220,256
Cost of sales	23,075	(240)	22,835	45,191	1,791	46,982
Gross profit	90,325	(1,613)	88,712	169,571	3,703	173,274

Sales and marketing	51,614	(85)	51,529	101,975	(178)	101,797
Other operating expenses	30,159	—	30,159	56,580	—	56,580
Operating income	$8,552	$(1,528)	$7,024	$11,016	$3,881	$14,897
Income tax expense	(1,694)	606	(1,088)	(5,612)	(849)	(6,461)
Net income from continuing operations	$1,855	$(922)	$933	$3,130	$3,032	$6,162
Net income from continuing operations per common share—basic	$0.10	$(0.05)	$0.05	$0.17	$0.16	$0.33
Net income from continuing operations per common share—diluted	$0.10	$(0.05)	$0.05	$0.16	$0.16	$0.32

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Revenue Recognition Under Topic 606

The Company accounts for a contract when there is approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance, and collectability of consideration is probable. The Company's contracts may contain one or more performance obligations. If a contract contains more than one performance obligation, the Company allocates the total transaction price to each of the performance obligations based upon the observable standalone selling price of the promised goods or services underlying each performance obligation. The Company recognizes revenue when control of the promised goods or services is transferred to the customer, which typically occurs at a point in time upon shipment, delivery, or utilization, in an amount that reflects the consideration which the Company expects to be entitled in exchange for the promised goods or services. The amount the Company expects to be entitled to in exchange for the goods or services reflects any fixed amount stated per the contract and estimates for any variable consideration, such as discounts, to the extent that is it probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

BioStim

BioStim revenue is largely attributable to the U.S. and is comprised of third-party payor transactions and wholesale revenue.

The largest portion of BioStim revenue is derived from third-party payors. This includes commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of the Company's stimulation products. The customer obtains control and revenue is recognized when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment. Adoption of Topic 606 had an immaterial impact to the BioStim SBU.

Wholesale revenue is related to the sale of the Company's bone growth stimulators directly to healthcare providers. Wholesale revenues are typically recognized upon shipment and receipt of a confirming purchase order, which is when the customer obtains control of the promised goods.

Extremity Fixation and Spine Fixation

Extremity Fixation and Spine Fixation products are distributed world-wide, with U.S. sales largely comprised of commercial revenue and international sales derived from commercial sales and through stocking distributor arrangements.

Commercial revenue is related to the sale of the Company's internal and external fixation products, generally representing hospital customers. The customer obtains control and revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital.

Certain revenue within the Extremity Fixation and Spine Fixation SBUs are derived from stocking distributors, who purchase the Company's products and then re-sell them directly to customers, such as hospitals. For revenue from stocking distributor arrangements, subsequent to the adoption of Topic 606 effective January 1, 2018, the Company

recognizes revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price with stocking distributors is estimated based upon the Company's historical collection experience with the stocking distributor. To derive this estimate, the Company analyzes twelve months of historical invoices by stocking distributor and the subsequent collections on those invoices, for a period of up to 24 months subsequent to the invoice date. This percentage, which is specific to each stocking distributor, is then used to calculate the transaction price. Cost of sales is also recorded upon transfer of control of the product to the customer.

Prior to the adoption of Topic 606, or for all periods presented prior to January 1, 2018, the Company recognized revenue from stocking distributor arrangements once the product was delivered to the end customer (the "sell-through method"). Because the Company did not have reliable information about when its distributors sold the product through to end customers, the Company used cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company was legally entitled to the accounts receivable at the time of shipment, the Company did not recognize accounts receivables or any corresponding deferred revenues at the time of shipment associated with stocking distributor transactions for which revenue was recognized on the sell-through method. The Company also considered whether to match the related cost of sales with revenue or to recognize cost of sales upon shipment. In making this assessment, the Company considered the financial viability

of its stocking distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped was reasonably assured at the time of shipment to these stocking distributors. In instances where the stocking distributor was determined to be financially viable, the Company deferred the costs of sales until the revenue was recognized.

Biologics

Biologics revenue is largely attributable to the U.S. and is primarily related to a collaborative arrangement with MTF Biologics (“MTF”), which extends through July 28, 2027, through which the Company markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE. Under the terms of the agreement, MTF sources the tissue, processes it to create the bone growth matrix, packages and delivers it to the customer in accordance with orders received from the Company. The Company has exclusive global marketing rights for the Trinity Evolution and Trinity ELITE tissues as well as non-exclusive marketing rights for other products, and receives marketing fees from MTF based on total sales. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes these marketing service fees on a net basis within net sales upon shipment of the product to the customer. Adoption of Topic 606 had an immaterial impact to the Biologics SBU.

Product Sales and Marketing Service Fees

The table below presents net sales, which includes product sales and marketing service fees, for the three and six months ended June 30, 2018 and 2017.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2018	2017	2018	2017
Product sales	$97,453	$93,908	$192,342	$182,309
Marketing service fees	14,094	15,034	27,914	29,371
Net sales	$111,547	$108,942	$220,256	$211,680

Product sales primarily consist of the sale of bone growth stimulation devices and internal and external fixation products. Marketing service fees are received from MTF based on total sales of biologics tissues and relates solely to the Biologics SBU. Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs for products shipped to customers are included in cost of sales.

Trade Accounts Receivable and Allowances

Payment terms vary by the type and location of the Company’s customers and the products or services offered. The term between invoicing and when payment is due is not significant. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. The Company’s estimates are periodically tested against actual collection experience.

Other Contract Assets

The Company’s contract assets, excluding trade accounts receivable (“other contract assets”), largely consist of payments made to certain distributors to obtain contracts, gain access to customers in certain territories, and to provide the

benefit of the exclusive distribution of Orthofix products. Other contract assets are included in other long-term assets and were $1.2 million and $1.0 million as of June 30, 2018, and December 31, 2017, respectively.

Other contract assets are amortized on a straight-line basis over the term of the related contract. There were no changes to such treatment as a result of adoption of Topic 606. No impairments were incurred for other contract assets in 2018 or 2017. Further, the Company has applied the practical expedient allowed within the guidance to expense sales commissions when incurred as the amortization period would be for one year or less.

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)	2018	2017	Change
BioStim	$48,211	$47,174	2.2 %
Spine Fixation	23,880	21,360	11.8 %
Biologics	14,668	15,661	-6.3 %
Extremity Fixation	24,788	24,747	0.2 %
Net sales	$111,547	$108,942	2.4 %

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2018	2017	Change
BioStim	$94,374	$91,713	2.9 %
Spine Fixation	44,587	40,627	9.7 %
Biologics	29,003	30,648	-5.4 %
Extremity Fixation	52,292	48,692	7.4 %
Net sales	$220,256	$211,680	4.1 %

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)	2018	2017	2018	2017
BioStim	$21,298	$19,469	$40,244	$36,602
Spine Fixation	2,887	2,696	4,148	4,703
Biologics	6,247	6,470	12,327	12,641
Extremity Fixation	7,002	6,766	15,160	13,178
Corporate	(251)	(107)	(402)	(205)
Non-GAAP net margin	$37,183	$35,294	$71,477	$66,919
General and administrative	22,268	20,409	41,752	38,691
Research and development	7,891	6,887	14,828	14,311
Operating income	$7,024	$7,998	$14,897	$13,917
Interest income (expense), net	(251)	76	(434)	121

Other income (expense), net	(4,752)	585	(1,840)	(3,763)
Income before income taxes	$2,021	$8,659	$12,623	$10,275

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Geographical information

The table below present net sales by geographic destination for each reporting unit and for the consolidated Company:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(U.S. Dollars, in thousands)	2018	2017	2018	2017
BioStim				
U.S.	$48,202	$47,162	$94,339	$91,701
International	9	12	35	12
Total BioStim	48,211	47,174	94,374	91,713
Spine Fixation				
U.S.	18,853	18,050	36,432	34,085
International	5,027	3,310	8,155	6,542
Total Spine Fixation	23,880	21,360	44,587	40,627
Biologics				
U.S.	14,667	15,651	28,989	30,614
International	1	10	14	34
Total Biologics	14,668	15,661	29,003	30,648
Extremity Fixation				
U.S.	7,023	6,741	13,939	13,320
International	17,765	18,006	38,353	35,372
Total Extremity Fixation	24,788	24,747	52,292	48,692
Consolidated				
U.S.	88,745	87,604	173,699	169,720
International	22,802	21,338	46,557	41,960
Net sales	$111,547	$108,942	$220,256	$211,680

10. Share-based compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(U.S. Dollars, in thousands)	2018	2017	2018	2017
Cost of sales	$132	$137	$257	$286
Sales and marketing	473	319	922	679
General and administrative	4,249	2,005	7,294	4,107
Research and development	361	215	658	420
	$5,215	$2,676	$9,131	$5,492

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2018	2017	Six Months Ended June 30, 2018	2017
Stock options	$1,241	$523	$1,863	$1,118
Time-based restricted stock awards and units	1,789	1,239	3,236	2,531
Performance-based restricted stock awards	270	113	759	225
Performance-based and market-based restricted stock units	1,604	472	2,557	938
Stock purchase plan	311	329	716	680
	$5,215	$2,676	$9,131	$5,492

During the three months ended June 30, 2018 and 2017, the Company issued 80,444 and 76,596 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, 2018 and 2017, the Company issued 206,955 and 291,275 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, 2018 and 2017, the effective tax rate on continuing operations was 53.8% and 45.3%, respectively. For the six months ended June 30, 2018 and 2017, the effective tax rate on continuing operations was 51.2% and 76.4%, respectively. The primary factors affecting the Company's effective tax rate for the three and six months ended June 30, 2018, were the lower U.S. statutory tax rate enacted in December 2017, 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.

During the first quarter of 2018, the Internal Revenue Service concluded an examination of the Company's federal income tax return for 2012 with no material impact on the financial statements. In November 2017, the Company was notified of an examination of its federal income tax return for 2015. The Company cannot reasonably determine if this examination, or any state and local tax examinations, will have a material impact on its financial statements and cannot predict the timing regarding resolution of these tax examinations. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits related to the resolution of federal, state and foreign matters could be reduced by $2.1 million to $4.1 million as audits close and statutes expire.

In the fourth quarter of 2017, the Company recorded tax expense of $8.3 million that represents what it believes is the impact of the enactment of the Tax Act. The expense was based on currently available information and interpretations, which are continuing to evolve, and as a result, the expense is considered provisional. The Company has continued to analyze additional information and guidance related to the Tax Act as supplemental legislation, regulatory guidance, or evolving technical interpretations become available. Based on supplemental legislation issued during 2018, the Company recorded a tax benefit of $0.5 million during the three and six months ended June 30, 2018, respectively. The Company will continue to refine such amounts within the measurement period as provided by Staff

Accounting Bulletin No. 118 and expects to complete its analysis no later than the fourth quarter of 2018.

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12. Earnings per share ("EPS")

The Company uses the two-class method of computing basic EPS due to the existence of non-vested restricted stock awards with nonforfeitable rights to dividends or dividend equivalents (referred to as participating securities). For the three and six months ended June 30, 2018 and 2017, no significant adjustments were made to net income 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,	
	2018	2017	2018	2017
Weighted average common shares-basic	18,413,756	18,050,551	18,409,331	18,015,308
Effect of dilutive securities				
Unexercised stock options and stock purchase plan	327,171	156,109	318,047	115,560
Unvested restricted stock awards and units	94,633	136,378	83,978	157,182
Weighted average common shares-diluted	18,835,560	18,343,038	18,811,356	18,288,050

There were 413,296 and 462,146 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, 2018 and 2017, respectively, and 259,470 and 506,964 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, 2018 and 2017, 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.

13. Subsequent events

On July 31, 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware (the "Domestication") in accordance with the conversion procedures of Articles 304 and 305 of Book 2 of the Curaçao Civil Code and the domestication procedures of Section 388 of the Delaware General Corporation Law. The Company's shareholders approved a proposal to adopt a shareholders' resolution authorizing the Domestication at the Company's 2018 Annual General Meeting of Shareholders held on July 17, 2018 (the "Annual General Meeting") by the affirmative vote of shareholders representing an absolute majority of the outstanding common shares of the Company as of the record date for the Annual General Meeting.

Upon the effectiveness of the Domestication, each common share of Orthofix International N.V. was automatically converted into one share of common stock of Orthofix Medical Inc. The Company's common stock continues to be traded on the Nasdaq Global Select Market under the symbol "OFIX."

On July 31, 2018, the Company amended and restated its existing Credit Agreement with JPMorgan, the Administrative Agent, and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement. The First Amended and Restated Credit Agreement is substantially the same as the existing Credit Agreement, except for certain amendments to, among other things, (i) effectuate the domestication of the Company from a Curaçao company to a Delaware corporation, (ii) limit the pledge by the Company and each domestic subsidiary of the Company of

equity interests in their respective first tier foreign subsidiaries to 65% of the voting interests in such foreign subsidiaries, (iii) limit the guarantee and joint and several obligations of each subsidiary guarantor that is a foreign subsidiary so that such foreign subsidiary guarantors are only providing guarantees, or are jointly and severally obligated, for obligations of other foreign subsidiaries, and (iv) limit the secured obligations that are secured by collateral provided by subsidiary guarantors that are foreign subsidiaries to secured obligations of foreign subsidiaries.

In addition, during July 2018, a court in a pending legal action issued an order resulting in the freezing of approximately $2.5 million in cash. Orthofix contests the underlying basis for the order.

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

The following discussion and analysis of Orthofix Medical Inc.'s (previously Orthofix International N.V. and sometimes referred to as "we," "us" or "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

We are a global medical device company focused on musculoskeletal products and therapies. Headquartered in Lewisville, Texas, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Spine Fixation, Biologics, and Extremity Fixation. Our products are widely distributed by our sales representatives and distributors.

Notable highlights and achievements in the second quarter of 2018 include the following:

- Net sales were $111.5 million, an increase of 2.4% on a reported basis and 1.3% on a constant currency basis
- Increase in non-GAAP net margin of $1.9 million, or 5.4%, and an increase as a percentage of sales from 32.4% in the second quarter of 2017 to 33.3% in the second quarter of 2018
- Completed the acquisition of Spinal Kinetics, a developer and manufacturer of artificial cervical and lumbar discs

Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(%)	(%)	(%)	(%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	20.5	21.3	21.3	21.6
Gross profit	79.5	78.7	78.7	78.4
Sales and marketing	46.2	46.3	46.2	46.8
General and administrative	20.0	18.7	19.0	18.3
Research and development	7.0	6.4	6.7	6.7
Operating income	6.3	7.3	6.8	6.6
Net income from continuing operations	0.8	4.3	2.8	1.1

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)	2018	2017	Reported	Constant Currency
BioStim	$48,211	$47,174	2.2 %	2.2 %
Spine Fixation	23,880	21,360	11.8 %	11.3 %
Biologics	14,668	15,661	-6.3 %	-6.3 %
Extremity Fixation	24,788	24,747	0.2 %	-4.0 %
Net sales	$111,547	$108,942	2.4 %	1.3 %

	Six Months Ended		Percentage	
	June 30,		Change	
(U.S. Dollars, in thousands)	2018	2017	Reported	Constant Currency
BioStim	$94,374	$91,713	2.9 %	2.9 %
Spine Fixation	44,587	40,627	9.7 %	9.4 %
Biologics	29,003	30,648	-5.4%	-5.4 %
Extremity Fixation	52,292	48,692	7.4 %	0.1 %
Net sales	$220,256	$211,680	4.1 %	2.3 %

BioStim

BioStim manufactures, distributes, sells, and provides support services for market leading devices that enhance bone fusion. BioStim uses distributors and sales representatives to sell its devices and provide associated services to hospitals, healthcare providers, and patients.

Three months ended June 30, 2018 compared to 2017

Net sales increased $1.0 million or 2.2%

- Increase driven by an increase in transacted sales driven by the execution of our commercial strategies and continued leverage of our recently launched next generation products supported by our STIM On Track mobile application

Six months ended June 30, 2018 compared to 2017

Net sales increased $2.7 million or 2.9%

- Increase driven by an increase in transacted sales driven by the execution of our commercial strategies and continued leverage of our recently launched next generation products supported by our STIM On Track mobile application

Spine Fixation

Spine Fixation designs, develops and markets a broad 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 and healthcare providers.

Three months ended June 30, 2018 compared to 2017

Net sales increased $2.5 million or 11.8%

- Increase of $2.3 million associated with the acquisition of Spinal Kinetics during the second quarter of 2018
- Increase in U.S. sales due to the addition of new distributor partners over the past twelve months and from the continued uptake of recent product introductions

Six months ended June 30, 2018 compared to 2017

Net sales increased $4.0 million or 9.7%

- Increase of $2.3 million associated with the acquisition of Spinal Kinetics during the second quarter of 2018
-

- Increase in U.S. sales due to the addition of new distributor partners over the past twelve months and from the continued uptake of recent product introductions

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 to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives.

Three months ended June 30, 2018 compared to 2017

Net sales decreased $1.0 million or 6.3%

- Decrease largely driven by a contractual reduction in the fee we receive for marketing service fees for Trinity tissues from MTF Biologics and due to a modest increase in pricing pressure for Trinity tissues
- Partially offset by a slight increase in volume for Trinity tissues

Six months ended June 30, 2018 compared to 2017

Net sales decreased $1.6 million or 5.4%

- Decrease largely driven by a contractual reduction in the fee we receive for marketing service fees for Trinity tissues from MTF Biologics and due to a modest increase in pricing pressure for Trinity tissues
- Partially offset by a slight increase in volume for Trinity tissues

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 and health providers.

Three months ended June 30, 2018 compared to 2017

Net sales increased by less than $0.1 million or 0.2%

- Increase due to the change in foreign currency exchange rates, which had a positive impact on 2018 net sales of $1.0 million
- Offset by a decrease in international sales largely relating to a higher than normal amount of orders received late in the second quarter of 2018 that did not ship until the third quarter of 2018

Six months ended June 30, 2018 compared to 2017

Net sales increased $3.6 million or 7.4%

- Increase largely due to the change in foreign currency exchange rates, which had a positive impact on 2018 net sales of $3.6 million

Gross Profit and Non-GAAP Net Margin

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2018	2017	% Change	2018	2017	% Change
Gross profit	$88,712	$85,765	3.4 %	$173,274	$165,922	4.4 %
Sales and marketing	(51,529)	(50,471)	2.1 %	(101,797)	(99,003)	2.8 %
Non-GAAP net margin	$37,183	$35,294	5.4 %	$71,477	$66,919	6.8 %
Gross margin	79.5 %	78.7 %	0.8 %	78.7 %	78.4 %	0.3 %
	33.3 %	32.4 %	0.9 %	32.5 %	31.6 %	0.9 %

Non-GAAP net margin as a percentage of
net sales
Three months ended June 30, 2018 compared to 2017

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 $2.9 million, primarily due to the growth in net sales with gross margin improving from 78.7% to 79.5%, driven by continued improvement related to inventory management initiatives, partially offset by the addition of Spinal Kinetics acquisition-related inventory fair value adjustments
- Sales and marketing expense increased $1.1 million, primarily due to the increase in net sales as sales and marketing expense as a percentage of net sales remained largely consistent

- Non-GAAP net margin increased by $1.9 million as a result of the changes in gross profit and sales and marketing expense

Six months ended June 30, 2018 compared to 2017

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 $7.4 million, primarily due to the growth in net sales with gross margin improving from 78.4% to 78.7%, driven by continued improvement related to inventory management initiatives, partially offset by the addition of Spinal Kinetics acquisition-related inventory fair value adjustments
- Sales and marketing expense increased $2.8 million, primarily due to higher commission and compensation-related expenses in the first six months of 2018 due to the increase in net sales; however, sales and marketing expenses decreased as a percentage of sales, largely due to decreased spending across all SBUs for seminars and other sales-related meetings
- Non-GAAP net margin increased by $4.6 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)	2018	2017	% Change	2018	2017	% Change
BioStim	$21,298	$19,469	9.4 %	$40,244	$36,602	10.0 %
Spine Fixation	2,887	2,696	7.1 %	4,148	4,703	-11.8 %
Biologics	6,247	6,470	-3.4 %	12,327	12,641	-2.5 %
Extremity Fixation	7,002	6,766	3.5 %	15,160	13,178	15.0 %
Corporate	(251)	(107)	134.6 %	(402)	(205)	96.1 %
Non-GAAP net margin	$37,183	$35,294	5.4 %	$71,477	$66,919	6.8 %

General and Administrative Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2018	2017	% Change	2018	2017	% Change
General and administrative	$22,268	$20,409	9.1 %	$41,752	$38,691	7.9 %
As a percentage of net sales	20.0 %	18.7 %	1.3 %	19.0 %	18.3 %	0.7 %

Three months ended June 30, 2018 compared to 2017

General and administrative expense increased $1.9 million

- Increase in share-based compensation expense of $2.2 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in timing of our annual grant to executives and key

personnel

- Increase of $2.1 million in expenses associated with strategic investments, such as our due diligence and integration efforts in connection with the Spinal Kinetics acquisition and expenditures to move the domicile of the Company
- Partially offset by decreases in certain compensation costs of $2.4 million, of which a portion is a result of our recent restructuring and optimization initiatives

Six months ended June 30, 2018 compared to 2017

General and administrative expense increased $3.1 million

- Increase of $3.8 million in expenses associated with strategic investments, such as our due diligence and integration efforts in connection with the Spinal Kinetics acquisition and expenditures to move the domicile of the Company
- Increase in share-based compensation expense of $3.2 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in timing of our annual grant to executives and key personnel
- Partially offset by decreases in certain compensation costs of $2.9 million, of which a portion is a result of our recent restructuring and optimization initiatives, and a decrease in other core general and administrative costs, including professional fees, of $1.0 million

Research and Development Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2018	2017	% Change	Six Months Ended June 30, 2018	2017	% Change
Research and development	$7,891	$6,887	14.6 %	$14,828	$14,311	3.6 %
As a percentage of net sales	7.1 %	6.3 %	0.8 %	6.7 %	6.8 %	-0.1 %

Three months ended June 30, 2018 compared to 2017

Research and development expense increased $1.0 million

- Increase in research and development costs largely attributable to the Spinal Kinetics acquisition and the regulatory efforts associated with the U.S. Food and Drug Administration ("FDA") premarket approval of the M6 Cervical Disc.

Six months ended June 30, 2018 compared to 2017

Research and development expense increased $0.5 million

- Increase in research and development costs largely attributable to the Spinal Kinetics acquisition and the regulatory efforts associated with the FDA premarket approval of the M6 Cervical Disc
- Partially offset by a decrease associated with cost savings from our 2017 U.S. restructuring initiative

Non-operating Income and Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30, 2018	2017	% Change	Six Months Ended June 30, 2018	2017	% Change
Interest income (expense), net	$(251)	$76	-430.3 %	$(434)	$121	-458.7 %
Other income (expense), net	(4,752)	585	-912.3 %	(1,840)	(3,763)	-51.1 %

Three months ended June 30, 2018 compared to 2017

Other income (expense) decreased $5.3 million

- Decrease of $3.9 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of $3.3 million in the second quarter of 2018 compared to a gain of $0.6 million in the second quarter of 2017
- Decrease of $1.1 million from the revaluation of contingent consideration associated with the Spinal Kinetics acquisition

Six months ended June 30, 2018 compared to 2017

Other income (expense) increased $1.9 million

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Increase of $5.6 million associated with an other-than-temporary impairment on the eNeura debt security during the first quarter of 2017

- Increase of $1.5 million relating to an unrealized gain in 2018 associated with the increase in fair value of our equity holdings and warrants in Bone Biologics
- Partially offset by a decrease of $3.8 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurment loss of $2.2 million in 2018 compared to a gain of $1.6 million in 2017
- Further offset by expense of $1.1 million from the revaluation of contingent consideration associated with the Spinal Kinetics acquisition

Income Taxes

	Three Months Ended June 30,			Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2018	2017	% Change	2018	2017	% Change
Income tax expense	$1,088	$3,924	-72.3 %	$6,461	$7,848	-17.7 %
Effective tax rate	53.8 %	45.3 %	8.5 %	51.2 %	76.4 %	-25.2 %

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Three months ended June 30, 2018 compared to 2017

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

- Decrease in pre-tax earnings
- Offset by decrease in the U.S. statutory tax rate from 35% to 21%

The primary factors affecting our effective tax rate for the second quarter of 2018 are as follows:

- The mix of earnings among tax jurisdictions
- Current period losses in jurisdictions where we do not currently receive a tax benefit
- Certain financial expenses not deductible for tax purposes

Six months ended June 30, 2018 compared to 2017

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

- Decrease in the U.S. statutory tax rate from 35% to 21%
- The mix of earnings among tax jurisdictions

The primary factors affecting our effective tax rate for the six months ended June 30, 2018 are as follows:

- The mix of earnings among tax jurisdictions
- Current period losses in jurisdictions where we do not currently receive a tax benefit
- Certain financial expenses not deductible for tax purposes

Liquidity and Capital Resources

Cash and cash equivalents at June 30, 2018, were $45.7 million compared to $81.2 million at December 31, 2017, with the decrease largely a result of cash paid in connection with the Spinal Kinetics acquisition.

	Six Months Ended June 30,		
(U.S. Dollars, in thousands)	2018	2017	Change
Net cash from operating activities	$13,032	$(4,642)	$17,674
Net cash from investing activities	(51,549)	(8,119)	(43,430)
Net cash from financing activities	3,685	2,431	1,254
Effect of exchange rate changes on cash	(639)	719	(1,358)
Net change in cash and cash equivalents	$(35,471)	$(9,611)	$(25,860)

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)	2018	2017	Change
Net cash from operating activities	$13,032	$(4,642)	$17,674
Capital expenditures	(6,652)	(8,593)	1,941
Free cash flow	$6,380	$(13,235)	$19,615

Operating Activities

Cash flows from operating activities increased $17.7 million

- Increase in net income of $5.0 million
- Net decrease of $8.4 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 taxes, depreciation and amortization, changes in the fair value of our investments and contingent consideration, and share-based compensation expense

- Net increase of $21.1 million relating to changes in working capital accounts, primarily attributable to changes in inventories as a result of improved inventory management initiatives put into place in 2017 and 2018

Two of our primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 61 days at June 30, 2018 compared to 51 days at June 30, 2017, with the increase largely attributable to our adoption of Accounting Standards Update ("ASU") 2014-09. Inventory turns remained consistent at 1.2 times as of June 30, 2018 and June 30, 2017.

Adoption of ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash

In November 2016, the FASB issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. The Company adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in a decrease in net cash from operating activities of $14.4 million for the six months ended June 30, 2017.

Investing Activities

Cash flows from investing activities decreased $43.4 million

- Decrease of $43.7 million associated with cash paid in relation to the Spinal Kinetics acquisition, net of cash acquired, which closed on April 30, 2018
- Decrease of $0.7 million associated with the acquisition of certain intangible assets in a transaction with a former distributor during the first quarter of 2018
- Decrease of $0.5 million due to our additional investment in Bone Biologics, Inc. during 2018
- Decrease of $0.5 million due to proceeds received in 2017 upon the maturity of certain time-based deposits
- Partially offset by a reduction in capital expenditures of $1.9 million

Financing Activities

Cash flows from financing activities increased $1.3 million

- Increase in net proceeds of $1.6 million from the issuance of common shares
- Partially offset by a decrease in other financing cash flows of $0.4 million

Credit Facilities

On July 31, 2018, the Company amended and restated its existing Credit Agreement with JPMorgan, the Administrative Agent, and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement. The First Amended and Restated Credit Agreement is substantially the same as the existing Credit Agreement, except for certain amendments to, among other things, (i) effectuate the domestication of the Company from a Curaçao company to a Delaware corporation, (ii) limit the pledge by the Company and each domestic subsidiary of the Company of equity interests in their respective first tier foreign subsidiaries to 65% of the voting interests in such foreign subsidiaries, (iii) limit the guarantee and joint and several obligations of each subsidiary guarantor that is a foreign subsidiary so that such foreign subsidiary guarantors are only providing guarantees, or are jointly and severally obligated, for obligations of other foreign subsidiaries, and (iv) limit the secured obligations that are secured by collateral provided by subsidiary guarantors that are foreign subsidiaries to secured obligations of foreign subsidiaries.

Other

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

Spinal Kinetics Acquisition

As consideration for the Spinal Kinetics acquisition, we agreed to pay an aggregate of $45.0 million in cash, subject to certain adjustments, upon closing plus milestone payments in the future of up to $60.0 million in cash. We closed on the acquisition on April 30, 2018 and paid the $45.0 million of cash, adjusted for certain items, due at close with cash on hand. The milestone payments include (i) up to $15.0 million for the FDA Milestone and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The fair value of the contingent consideration arrangement as of June 30, 2018 was $26.6 million; however, the actual amount ultimately paid could be higher or lower than the