

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 September 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

(State or other jurisdiction of
incorporation or organization)

**3451 Plano Parkway,
Lewisville, Texas**
(Address of principal executive offices)

98-1340767

(I.R.S. Employer
Identification No.)

75056
(Zip Code)

(214) 937-2000

(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 every Interactive Data File required to be submitted 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 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 ☒
Non-Accelerated filer ☐

Accelerated filer ☐
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 October 26, 2018, 18,920,827 shares of common stock were issued and outstanding.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (“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 comparable 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 Securities and Exchange Commission (“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

	September 30, 2018	December 31, 2017
(U.S. Dollars, in thousands, except share data)	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 53,783	\$ 81,157
Restricted cash	2,459	—
Accounts receivable, net of allowances of \$8,039 and \$8,405, respectively	74,356	63,437
Inventories	79,895	81,330
Prepaid expenses and other current assets	34,517	25,877
Total current assets	245,010	251,801
Property, plant and equipment, net	43,575	45,139
Intangible assets, net	51,637	10,461
Goodwill	70,747	53,565
Deferred income taxes	36,030	23,315
Other long-term assets	3,166	21,073
Total assets	\$ 450,165	\$ 405,354
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	\$ 15,426	\$ 18,111
Other current liabilities	61,387	61,295
Total current liabilities	76,813	79,406
Other long-term liabilities	50,002	29,340
Total liabilities	126,815	108,746
Contingencies (Note 6)		
Shareholders' equity		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,536,716 and 18,278,833 issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	1,854	1,828
Additional paid-in capital	238,422	220,591
Retained earnings	78,207	70,402
Accumulated other comprehensive income	4,867	3,787
Total shareholders' equity	323,350	296,608
Total liabilities and shareholders' equity	\$ 450,165	\$ 405,354

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

ORTHOFIX MEDICAL INC.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited, U.S. Dollars, in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net sales	\$ 111,708	\$ 105,247	\$ 331,964	\$ 316,927
Cost of sales	24,020	23,717	71,002	69,475
Gross profit	87,688	81,530	260,962	247,452
Sales and marketing	49,898	47,493	151,695	146,496
General and administrative	22,705	18,068	64,457	56,759
Research and development	9,598	6,935	24,426	21,246
Changes in fair value of contingent consideration	1,580	—	2,689	—
Operating income	3,907	9,034	17,695	22,951
Interest income (expense), net	(181)	(15)	(615)	106
Other income (expense), net	(5,054)	479	(5,785)	(3,284)
Income (loss) before income taxes	(1,328)	9,498	11,295	19,773
Income tax benefit (expense)	115	(6,150)	(6,346)	(13,998)
Net income (loss) from continuing operations	(1,213)	3,348	4,949	5,775
Discontinued operations (Note 6)				
Income (loss) from discontinued operations	—	65	(3)	(1,762)
Income tax benefit (expense)	2	43	(6)	642
Net income (loss) from discontinued operations	2	108	(9)	(1,120)
Net income (loss)	\$ (1,211)	\$ 3,456	\$ 4,940	\$ 4,655
Net income (loss) per common share—basic				
Net income (loss) from continuing operations	\$ (0.07)	\$ 0.18	\$ 0.26	\$ 0.32
Net income (loss) from discontinued operations	—	0.01	—	(0.06)
Net income (loss) per common share—basic	\$ (0.07)	\$ 0.19	\$ 0.26	\$ 0.26
Net income (loss) per common share—diluted				
Net income (loss) from continuing operations	\$ (0.07)	\$ 0.18	\$ 0.26	\$ 0.31
Net income (loss) from discontinued operations	—	0.01	—	(0.06)
Net income (loss) per common share—diluted	\$ (0.07)	\$ 0.19	\$ 0.26	\$ 0.25
Weighted average number of common shares:				
Basic	18,562,204	18,180,845	18,460,848	18,071,093
Diluted	18,562,204	18,572,791	18,864,169	18,394,542
Other comprehensive income, before tax				
Unrealized gain (loss) on debt securities	1,240	—	3,200	\$ (3,220)
Reclassification adjustment for loss on debt securities in net income	—	—	—	5,585
Currency translation adjustment	(844)	1,111	(1,322)	3,993
Other comprehensive income before tax	396	1,111	1,878	6,358
Income tax related to items of other comprehensive income	(366)	—	(798)	(900)
Other comprehensive income, net of tax	30	1,111	1,080	5,458
Comprehensive income (loss)	\$ (1,181)	\$ 4,567	\$ 6,020	\$ 10,113

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

ORTHOFIX MEDICAL INC.
Condensed Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
(Unaudited, U.S. Dollars, in thousands)	2018	2017
Cash flows from operating activities		
Net income	\$ 4,940	\$ 4,655
Adjustments to reconcile net income to net cash from operating activities		
Depreciation and amortization	13,661	15,421
Amortization of debt costs and other assets	818	1,072
Provision for doubtful accounts	(571)	1,555
Deferred income taxes	(5,082)	153
Share-based compensation	14,392	9,124
Other-than-temporary impairment on debt securities	—	5,585
Loss on valuation of equity securities	3,050	—
Change in fair value of contingent consideration	2,689	—
Other	1,040	823
Changes in operating assets and liabilities, net of effects of acquisition		
Accounts receivable	(225)	(4,302)
Inventories	6,880	(14,714)
Prepaid expenses and other current assets	1,498	1,377
Accounts payable	(2,788)	(2,233)
Other current liabilities	(13,130)	(11,639)
Other long-term assets and liabilities	1,657	2,248
Net cash from operating activities	28,829	9,125
Cash flows from investing activities		
Acquisition of business, net of cash acquired	(43,749)	—
Capital expenditures for property, plant and equipment	(9,586)	(11,441)
Capital expenditures for intangible assets	(1,138)	(1,849)
Asset acquisitions and other investments	(1,448)	—
Other investing activities	—	474
Net cash from investing activities	(55,921)	(12,816)
Cash flows from financing activities		
Proceeds from issuance of common shares	5,866	6,277
Payments related to withholdings for share-based compensation	(2,402)	(3,679)
Payment of debt issuance costs and other financing activities	(476)	—
Net cash from financing activities	2,988	2,598
Effect of exchange rate changes on cash	(811)	1,077
Net change in cash, cash equivalents, and restricted cash	(24,915)	(16)
Cash, cash equivalents, and restricted cash at the beginning of period	81,157	53,941
Cash, cash equivalents, and restricted cash at the end of period	\$ 56,242	\$ 53,925
Components of cash, cash equivalents and restricted cash at the end of period		
Cash and cash equivalents	\$ 53,783	\$ 53,925
Restricted cash	2,459	—
Cash, cash equivalents, and restricted cash at the end of period	\$ 56,242	\$ 53,925
Supplemental Disclosure of Cash Flow Information:		
Noncash investing activities:		
Purchase of intangible assets	\$ 1,581	\$ —
Contingent consideration recognized at acquisition date	25,491	—

The accompanying notes form an integral part of these 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 reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as 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 nine months ended September 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, contingent consideration, income taxes, and share-based compensation. Actual results could differ from these estimates.

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 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.”

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 Financial Accounting Standards Board (“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 Accounting Standards Codification (“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 during the first quarter of

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 were recorded within other current assets or long-term assets and other income (expense), of \$1.6 million, or \$0.09 per share before taxes, during the three months ended March 31, 2018. During the three months ended September 30, 2018, Bone Biologics completed a series of equity financing activities, which provided a new observable price change in an orderly transaction. As a result, the Company determined its investment to be impaired and recorded a charge of \$4.4 million during the third quarter of 2018. 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 operations and comprehensive income (loss) 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 an increase in net cash from operating activities of \$2.5 million for the nine months ended September 30, 2018 and a decrease in net cash from operating activities of \$14.4 million for the nine months ended September 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 certain transactions during the first and third quarters of 2018 for approximately \$1.9 million and \$0.7 million, respectively, as asset acquisitions rather than business combinations, as the sets 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 and other related updates)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach. An entity can choose to apply the provisions at the beginning of the earliest comparative period presented in the financial statements or at the beginning of the period of adoption. The Company expects to apply the provisions at the beginning of the period of adoption, beginning on January 1, 2019.	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. The Company is continuing to evaluate the potential impact to the Company's balance sheet, but expects to recognize lease assets and lease liabilities as of January 1, 2019, in excess of \$12 million. The Company does not expect material impacts to its consolidated statements of operations and comprehensive income (loss) or to the consolidated statements of cash flows. Additionally, the Company expects to materially change its disclosures to provide users more quantitative and qualitative information about the Company's leases, any significant judgments required in applying the ASU, and amounts recognized within the consolidated financial statements related to the Company's leases.
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, not to exceed the recorded amount of goodwill. Applied on a prospective basis, with early adoption permitted.	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.
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.

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Fair value measurement (ASU 2018-13)	Eliminates such disclosures as the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and adds new disclosure requirements for Level 3 measurements. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
Implementation costs in a cloud computing arrangement that is a service contract (ASU 2018-15)	Aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. Applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption.	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

Other recently issued accounting guidance

In August 2018, the Securities and Exchange Commission (the “SEC” or the “Commission”) issued SEC Final Rule Release No. 33-10532, *Disclosure Update and Simplification*, which amends certain of the Commission’s disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded, in light of other Commission disclosure requirements, U.S. GAAP, or changes in the information environment. However, in certain instances, the amendments expanded disclosure requirements, including those related to interim disclosures about changes in shareholders’ equity. As amended in the final rule, registrants must now analyze changes in shareholders’ equity, in the form of a reconciliation for the current year-to-date interim periods, with subtotals for each interim period. The final rule is effective for all filings submitted on or after November 5, 2018. As a result, the Company anticipates that it will present a Condensed Consolidated Statement of Changes in Shareholders’ Equity within its interim financial statements beginning in its Form 10-Q for the quarter ending March 31, 2019.

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 Spinal Implants 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 (the "FDA") grants approval of Spinal Kinetics' M6-C artificial cervical 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 \$28.2 million as of September 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 \$2.7 million was recorded as an operating expense labeled changes in fair value of contingent consideration. 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 of the acquisition date.

(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 and is not expected to be deductible for tax purposes. The \$17.2 million of goodwill recognized was assigned to the Spinal Implants 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, which the Company currently expects to occur mid-2019, the Company will determine the useful life of the asset and begin amortization.

The Company recognized \$0.3 million and \$3.3 million of acquisition related costs that were expensed during the three and nine months ended September 30, 2018, respectively. These costs are included in the condensed consolidated statements of operations and comprehensive income (loss) within general and administrative expenses. The Company's results of operations included \$2.9 million and \$5.2 million of revenue from Spinal Kinetics from the date of acquisition for the three and nine months ended September 30, 2018 and net loss of \$2.1 million and \$3.5 million from the date of acquisition for the three and nine months ended September 30, 2018 in the condensed consolidated statements of operations and comprehensive income (loss).

The following table presents the unaudited pro forma results for the three and nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net sales	\$ 111,708	\$ 109,019	\$ 336,882	\$ 328,182
Net income from continuing operations	78	1,415	7,055	448

3. Inventories

Inventories were as follows:

(U.S. Dollars, in thousands)	September 30, 2018	December 31, 2017
Raw materials	\$ 8,488	\$ 6,067
Work-in-process	11,774	12,487
Finished products	59,633	60,441
Deferred cost of sales	—	2,335
Inventories	\$ 79,895	\$ 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

On July 31, 2018, the Company amended and restated its previous Credit Agreement with JPMorgan Chase Bank, N.A. ("JPMorgan"), the Administrative Agent, and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement ("Amended Credit Agreement"). The Amended Credit Agreement is substantially the same as the previous 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.

As of September 30, 2018, the Company had no borrowings under the Amended Credit Agreement. In addition, the Company has no borrowings on its €5.8 million (\$6.7 million) available line of credit in Italy as of September 30, 2018. The Company is in compliance with all required financial covenants as of September 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)	September 30, 2018				December 31, 2017
	Level 1	Level 2	Level 3	Total	Total
Assets					
Collective trust funds	\$ —	\$ —	\$ —	\$ —	\$ 100
Treasury securities	520	—	—	520	556
Equity warrants	—	—	—	—	311
Equity securities	—	219	—	219	2,457
Debt security	—	—	19,250	19,250	16,050
Total	\$ 520	\$ 219	\$ 19,250	\$ 19,989	\$ 19,474
Liabilities					
Contingent consideration	\$ —	\$ —	\$ (28,180)	\$ (28,180)	\$ —
Deferred compensation plan	—	(1,291)	—	(1,291)	(1,379)
Total	\$ —	\$ (1,291)	\$ (28,180)	\$ (29,471)	\$ (1,379)

Equity Warrants and Securities

The Company holds investments in common stock and warrants to purchase shares of common stock of 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. During the first quarter of 2018, the Company made an additional investment in Bone Biologics through the purchase of an additional 25,000 shares of common stock, after giving effect to a reverse stock split subsequent to the purchase, for \$0.5 million.

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 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, based on an observable price in an orderly transaction during the three months ended March 31, 2018. During the three months ended September 30, 2018, Bone Biologics executed a series of equity financing activities which significantly diluted the Company's ownership interest in the outstanding stock. After considering the new observable prices in these equity financing activities, and after giving consideration to going concern issues disclosed by Bone Biologics, the Company determined this investment was impaired and recorded an impairment charge of \$4.4 million relating to its investments in Bone Biologics. These changes are classified within other income and expense.

The changes in valuation of these securities for the three months and nine months ended September 30, 2018 and 2017 are shown below:

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Equity securities and warrants beginning balance	\$ 4,668	\$ 2,768	\$ 2,768	\$ 2,768
Impact of adoption of ASU 2016-01 recognized in other income	—	—	1,629	—
Purchase of additional common stock	—	—	500	—
Fair value adjustments, expirations, and impairments recognized in other expense	(4,449)	—	(4,678)	—
Equity securities and warrants ending balance	\$ 219	\$ 2,768	\$ 219	\$ 2,768

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 September 30, 2018, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of \$19.3 million, an increase of \$3.2 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	3,200	2,365
Debt security at September 30	\$ 19,250	\$ 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 FDA grants approval of Spinal Kinetics' M6-C artificial cervical 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 \$28.2 million as of September 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 \$2.7 million was recorded as an operating expense labeled changes in fair value of contingent consideration. Approximately \$13.6 million of this liability is included within other current liabilities and \$14.6 million is included within other long-term liabilities.

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. The Company currently expects to obtain approval from the FDA mid-2019. 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 operating expenses	2,689
Contingent consideration at September 30	\$ 28,180

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, Inc. (“Breg”), a former subsidiary of the Company, 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 operations and comprehensive income (loss).

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 September 30, 2018, the Company has accrued €3.0 million (\$3.5 million) related to the IMDP, which it has classified within other long-term liabilities; however, the actual liability could be higher or lower than the amount accrued once the law has been clarified by the Italian authorities.

Brazil

In July 2018, the Federal Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority (CADE) inspected the offices of more than 30 companies, including Orthofix’s office in São Paulo, as part of an investigation into tender irregularities in the medical device industry. Before doing so, the authorities obtained a court order affecting Orthofix’s (and other companies’) local bank accounts resulting in the freezing of approximately \$2.5 million of Orthofix’s cash, which the Company reclassified to restricted cash. Orthofix contests the underlying basis for the order. Based on information known to date, the Company does not believe that the Brazilian authorities’ investigation will result in a material loss to the Company.

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	(1,322)	3,200	1,878
Income taxes	—	(798)	(798)
Balance at September 30, 2018	\$ (1,885)	\$ 6,752	\$ 4,867

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 nine months ended September 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 Topic 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 operations for the three and nine months ended September 30, 2018 as a result of the adoption of Topic 606.

(U.S. Dollars, in thousands)	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
	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	\$ 109,512	\$ 2,196	\$ 111,708	\$ 324,274	\$ 7,690	\$ 331,964
Cost of sales	23,784	236	24,020	68,975	2,027	71,002
Gross profit	85,728	1,960	87,688	255,299	5,663	260,962
Sales and marketing	49,766	132	49,898	151,741	(46)	151,695
Other operating expenses	33,883	—	33,883	91,572	—	91,572
Operating income	\$ 2,079	\$ 1,828	\$ 3,907	\$ 11,986	\$ 5,709	\$ 17,695
Income tax expense	677	(562)	115	(4,935)	(1,411)	(6,346)
Net income (loss) from continuing operations	\$ (2,479)	\$ 1,266	\$ (1,213)	\$ 651	\$ 4,298	\$ 4,949
Net income (loss) from continuing operations per common share —basic	\$ (0.13)	\$ 0.06	\$ (0.07)	\$ 0.04	\$ 0.22	\$ 0.26
Net income (loss) from continuing operations per common share —diluted	\$ (0.13)	\$ 0.06	\$ (0.07)	\$ 0.03	\$ 0.23	\$ 0.26

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 it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

Bone Growth Therapies

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

The largest portion of Bone Growth Therapies 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 Bone Growth Therapies reporting segment.

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.

Orthofix Extremities and Spinal Implants

Orthofix Extremities and Spinal Implants 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 revenues within the Orthofix Extremities and Spinal Implants reporting segments 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 reporting segment.

Product Sales and Marketing Service Fees

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

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales	\$ 97,604	\$ 90,645	\$ 289,946	\$ 272,954
Marketing service fees	14,104	14,602	42,018	43,973
Net sales	\$ 111,708	\$ 105,247	\$ 331,964	\$ 316,927

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 relate solely to the Biologics reporting segment. 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 \$1.1 million and \$1.0 million as of September 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 Company has four reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation). The tables below present net sales, which includes product sales and marketing service fees, by reporting segment:

Three Months Ended September 30,				
(U.S. Dollars, in thousands)	2018	2017	Change	
Bone Growth Therapies	\$ 48,059	\$ 44,427		8.2%
Spinal Implants	22,102	20,155		9.7%
Biologics	14,636	15,218		-3.8%
Orthofix Extremities	26,911	25,447		5.8%
Net sales	\$ 111,708	\$ 105,247		6.1%

Nine Months Ended September 30,				
(U.S. Dollars, in thousands)	2018	2017	Change	
Bone Growth Therapies	\$ 142,433	\$ 136,140		4.6%
Spinal Implants	66,689	60,782		9.7%
Biologics	43,639	45,866		-4.9%
Orthofix Extremities	79,203	74,139		6.8%
Net sales	\$ 331,964	\$ 316,927		4.7%

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:

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Bone Growth Therapies	\$ 21,151	\$ 18,285	\$ 61,395	\$ 54,887
Spinal Implants	1,812	2,122	5,960	6,825
Biologics	6,654	6,010	18,981	18,651
Orthofix Extremities	8,295	7,723	23,455	20,901
Corporate	(122)	(103)	(524)	(308)
Non-GAAP net margin	\$ 37,790	\$ 34,037	\$ 109,267	\$ 100,956
General and administrative	22,705	18,068	64,457	56,759
Research and development	9,598	6,935	24,426	21,246
Changes in fair value of contingent consideration	1,580	—	2,689	—
Operating income	\$ 3,907	\$ 9,034	\$ 17,695	\$ 22,951
Interest income (expense), net	(181)	(15)	(615)	106
Other income (expense), net	(5,054)	479	(5,785)	(3,284)
Income (loss) before income taxes	\$ (1,328)	\$ 9,498	\$ 11,295	\$ 19,773

Geographical information

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

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Bone Growth Therapies				
U.S.	\$ 48,039	\$ 44,427	\$ 142,378	\$ 136,128
International	20	—	55	12
Total Bone Growth Therapies	48,059	44,427	142,433	136,140
Spinal Implants				
U.S.	16,829	17,085	53,261	51,170
International	5,273	3,070	13,428	9,612
Total Spinal Implants	22,102	20,155	66,689	60,782
Biologics				
U.S.	14,634	15,202	43,623	45,816
International	2	16	16	50
Total Biologics	14,636	15,218	43,639	45,866
Orthofix Extremities				
U.S.	7,254	6,804	21,193	20,124
International	19,657	18,643	58,010	54,015
Total Orthofix Extremities	26,911	25,447	79,203	74,139
Consolidated				
U.S.	86,756	83,518	260,455	253,238
International	24,952	21,729	71,509	63,689
Net sales	\$ 111,708	\$ 105,247	\$ 331,964	\$ 316,927

10. Share-based compensation

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

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	\$ 151	\$ 151	\$ 408	\$ 437
Sales and marketing	514	394	1,436	1,073
General and administrative	4,194	2,828	11,488	6,935
Research and development	402	259	1,060	679
Total	\$ 5,261	\$ 3,632	\$ 14,392	\$ 9,124

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options	\$ 579	\$ 684	\$ 2,442	\$ 1,802
Time-based restricted stock awards and units	2,244	1,552	5,480	4,083
Performance-based restricted stock awards and units	734	115	1,493	340
Market-based restricted stock units	1,298	997	3,855	1,935
Stock purchase plan	406	284	1,122	964
Total	\$ 5,261	\$ 3,632	\$ 14,392	\$ 9,124

During the three months ended September 30, 2018 and 2017, the Company issued 50,928 and 93,486 shares, respectively, of common stock related to stock option exercises and the vesting of restricted stock awards. During the nine months ended September 30, 2018 and 2017, the Company issued 257,883 and 384,761 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 September 30, 2018 and 2017, the effective tax rate on continuing operations was 8.7% and 64.8%, respectively. For the nine months ended September 30, 2018 and 2017, the effective tax rate on continuing operations was 56.2% and 70.8%, respectively. The primary factors affecting the Company's effective tax rate for the three and nine months ended September 30, 2018, were the impairment of the Bone Biologics investment, the mix of earnings among tax jurisdictions, financial expenses not deductible for tax purposes, 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 \$4.4 million to \$6.6 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 guidance issued during 2018, the Company recorded a tax benefit of \$0.5 million during the first quarter. 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.

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 nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Weighted average common shares-basic	18,562,204	18,180,845	18,460,848	18,071,093
Effect of dilutive securities				
Unexercised stock options and stock purchase plan	—	249,667	312,320	164,716
Unvested restricted stock awards and units	—	142,279	91,001	158,733
Weighted average common shares-diluted	18,562,204	18,572,791	18,864,169	18,394,542

There were 2,088,843 and 503,757 weighted average outstanding stock options and restricted stock awards and units not included in the diluted EPS computation for the three months ended September 30, 2018 and 2017, respectively, and 359,172 and 534,288 weighted average outstanding stock options and restricted stock awards and units not included in the diluted EPS computation for the nine months ended September 30, 2018 and 2017, respectively, because inclusion of these awards was anti-dilutive, a loss from continuing operations for the three months ended September 30, 2018, or, for performance-based and market-based restricted stock awards and units, 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 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 reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation). Our products are widely distributed by our sales representatives and distributors.

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

- Net sales were \$111.7 million, an increase of 6.1% on a reported basis and 6.6% on a constant currency basis
- Increase in non-GAAP net margin of \$3.8 million, or 11.0%, and an increase as a percentage of sales from 32.3% in the third quarter of 2017 to 33.8% in the third quarter of 2018
- Completed a change in jurisdiction of organization from Curaçao to the State of Delaware

Results of Operations

The following table provides certain items in our condensed consolidated statements of operations and comprehensive income (loss) as a percent of net sales:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018 (%)	2017 (%)	2018 (%)	2017 (%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	21.5	22.5	21.4	21.9
Gross profit	78.5	77.5	78.6	78.1
Sales and marketing	44.7	45.1	45.7	46.3
General and administrative	20.3	17.2	19.4	17.9
Research and development	8.6	6.6	7.4	6.7
Changes in fair value of contingent consideration	1.4	—	0.8	—
Operating income	3.5	8.6	5.3	7.2
Net income (loss) from continuing operations	(1.1)	3.2	1.5	1.8

Net Sales by Reporting Segment

The following tables provide net sales by reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended September 30,		Percentage Change	
	2018	2017	Reported	Constant Currency
Bone Growth Therapies	\$ 48,059	\$ 44,427	8.2%	8.2%
Spinal Implants	22,102	20,155	9.7%	10.0%
Biologics	14,636	15,218	-3.8%	-3.8%
Orthofix Extremities	26,911	25,447	5.8%	7.5%
Net sales	\$ 111,708	\$ 105,247	6.1%	6.6%

(U.S. Dollars, in thousands)	Nine Months Ended September 30,		Percentage Change	
	2018	2017	Reported	Constant Currency
Bone Growth Therapies	\$ 142,433	\$ 136,140	4.6%	4.6%
Spinal Implants	66,689	60,782	9.7%	9.6%
Biologics	43,639	45,866	-4.9%	-4.9%
Orthofix Extremities	79,203	74,139	6.8%	2.6%
Net sales	\$ 331,964	\$ 316,927	4.7%	3.7%

Bone Growth Therapies

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

Three months ended September 30, 2018 compared to 2017

Net sales increased \$3.6 million or 8.2%

- Increase primarily driven by the execution of our commercial strategies and the continued leverage of our recently launched next generation products supported by our STIM On Track mobile application
- Increase of approximately \$1.0 million associated with the unusually late receipt of certain documentation necessary to convert orders to sales at the end of the second quarter, which transacted during the third quarter and did not recur at the end of the third quarter

Nine months ended September 30, 2018 compared to 2017

Net sales increased \$6.3 million or 4.6%

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

Spinal Implants

Spinal Implants designs, develops and markets a broad portfolio of implant products used in surgical procedures of the spine. Spinal Implants distributes its products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

Three months ended September 30, 2018 compared to 2017

Net sales increased \$1.9 million or 9.7%

- Increase of \$2.9 million driven by international sales of the M6 discs of Spinal Kinetics subsequent to the acquisition, which closed during the second quarter of 2018
- Partially offset by a decrease in legacy international sales of \$0.7 million due to recent disruption in sales leadership as well as variability in the timing of stocking distributor orders and payments
- Further offset by a decrease in U.S. sales of \$0.3 million due primarily to the disruption resulting from the ongoing spine business realignment and leadership transition, which is not expected to impact this business for more than a few quarters

Nine months ended September 30, 2018 compared to 2017

Net sales increased \$5.9 million or 9.7%

- Increase of \$5.2 million driven by international sales of the M6 discs of Spinal Kinetics subsequent to the acquisition, which closed during the second quarter of 2018
- Increase in U.S. sales of \$2.1 million due to the addition of new distributor partners during the first half of 2017 and from the uptake of recent product introductions

- Partially offset by a decrease in international sales of \$1.4 million due to variability in the timing of stocking distributor orders and payments

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 September 30, 2018 compared to 2017

Net sales decreased \$0.6 million or 3.8%

- Decrease of 7.6% primarily driven by a contractual reduction in the fee we receive for marketing service fees for Trinity tissues from MTF Biologics ("MTF") during the first quarter of 2018
- Partially offset by a 4.6% increase in volume for Trinity tissues

Nine months ended September 30, 2018 compared to 2017

Net sales decreased \$2.2 million or 4.9%

- Decrease of 5.6% primarily driven by a contractual reduction in the fee we receive for marketing service fees for Trinity tissues from MTF during the first quarter of 2018
- Partially offset by a slight increase in volume for Trinity tissues of 2.8%

Orthofix Extremities

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

Three months ended September 30, 2018 compared to 2017

Net sales increased \$1.5 million or 5.8%

- Increase of \$1.4 million attributed 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
- Increase of \$0.5 million within the U.S. due to continued distribution expansion and adoption of our TrueLok products
- Partially offset by the changes in foreign currency exchange rates, which had a negative impact on net sales for the three months of \$0.4 million

Nine months ended September 30, 2018 compared to 2017

Net sales increased \$5.1 million or 6.8%

- Increase largely due to the change in foreign currency exchange rates, which had a positive impact on net sales for the nine months of \$3.1 million
- Increase of \$1.1 million within the U.S. due to continued distribution expansion and adoption of our TrueLok products
- Increase in international sales of \$0.9 million, excluding the impact of changes in foreign currency exchange rates, due to continued expansion of our third-party distributors

Gross Profit and Non-GAAP Net Margin

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Gross profit	\$ 87,688	\$ 81,530	7.6%	\$ 260,962	\$ 247,452	5.5%
Sales and marketing	(49,898)	(47,493)	5.1%	(151,695)	(146,496)	3.5%
Non-GAAP net margin	\$ 37,790	\$ 34,037	11.0%	\$ 109,267	\$ 100,956	8.2%
Gross margin	78.5%	77.5%	1.0%	78.6%	78.1%	0.5%
Non-GAAP net margin as a percentage of net sales	33.8%	32.3%	1.5%	32.9%	31.9%	1.0%

Three months ended September 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 \$6.2 million, primarily due to the growth in net sales with gross margin improving from 77.5% to 78.5%, driven by costs savings from our 2017 U.S. restructuring initiative and 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 \$2.4 million, primarily due to the increase in net sales and partially offset by improvements in commission rates
- Non-GAAP net margin increased by \$3.8 million as a result of the changes in gross profit and sales and marketing expense

Nine months ended September 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 \$13.5 million, primarily due to the growth in net sales with gross margin improving from 78.1% to 78.6%, largely driven by changes in product mix and partially offset by the addition of Spinal Kinetics acquisition-related inventory fair value adjustments
- Sales and marketing expense increased \$5.2 million, primarily due to the increase in net sales and partially offset by improvements in commission rates
- Non-GAAP net margin increased by \$8.3 million as a result of the changes in gross profit and sales and marketing expense

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

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Bone Growth Therapies	\$ 21,151	\$ 18,285	15.7%	\$ 61,395	\$ 54,887	11.9%
Spinal Implants	1,812	2,122	-14.6%	5,960	6,825	-12.7%
Biologics	6,654	6,010	10.7%	18,981	18,651	1.8%
Orthofix Extremities	8,295	7,723	7.4%	23,455	20,901	12.2%
Corporate	(122)	(103)	18.4%	(524)	(308)	70.1%
Non-GAAP net margin	\$ 37,790	\$ 34,037	11.0%	\$ 109,267	\$ 100,956	8.2%

General and Administrative Expense

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
General and administrative	\$ 22,705	\$ 18,068	25.7%	\$ 64,457	\$ 56,759	13.6%
As a percentage of net sales	20.3%	17.2%	3.1%	19.4%	17.9%	1.5%

Three months ended September 30, 2018 compared to 2017

General and administrative expense increased \$4.6 million

- Increase of \$3.4 million in expenses associated with strategic investments, including 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 \$1.4 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in the timing of our annual grants to executives and key personnel

Nine months ended September 30, 2018 compared to 2017

General and administrative expense increased \$7.7 million

- Increase of \$7.2 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 \$4.6 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in the timing of our annual grants to executives and key personnel
- Partially offset by decreases in certain compensation-related costs of \$3.2 million, including bonus incentives, and a decrease in other core general and administrative costs, including professional fees, of \$0.9 million

Research and Development Expense

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Research and development	\$ 9,598	\$ 6,935	38.4%	\$ 24,426	\$ 21,246	15.0%
As a percentage of net sales	8.6%	6.6%	2.0%	7.4%	6.7%	0.7%

Three months ended September 30, 2018 compared to 2017

Research and development expense increased \$2.7 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

Nine months ended September 30, 2018 compared to 2017

Research and development expense increased \$3.2 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

Changes in Fair Value of Contingent Consideration

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Changes in fair value of contingent consideration	\$ 1,580	\$ —	100.0%	\$ 2,689	\$ —	100.0%
As a percentage of net sales	1.4%	0.0%	1.4%	0.8%	0.0%	0.8%

Three months and nine months ended September 30, 2018 compared to 2017

The fair value of contingent consideration increased \$1.6 million and \$2.7 million, respectively

- Changes relate to the fair value of the potential future milestone payments of up to \$60.0 million in cash associated with the Spinal Kinetics acquisition

Non-operating Income and Expense

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Interest income (expense), net	\$ (181)	\$ (15)	1106.7%	\$ (615)	\$ 106	-680.2%
Other income (expense), net	(5,054)	479	-1155.1%	(5,785)	(3,284)	76.2%

Three months ended September 30, 2018 compared to 2017

Other income (expense) decreased \$5.5 million

- Decrease of \$4.4 million from impairment of our equity holdings and warrants in Bone Biologics, Inc. ("Bone Biologics") common stock
- Decrease of \$1.4 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of \$0.6 million in the third quarter of 2018 compared to a gain of \$0.8 million in the third quarter of 2017

Nine months ended September 30, 2018 compared to 2017

Other income (expense) decreased \$2.5 million

- Decrease of \$5.2 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of \$2.8 million in 2018 compared to a gain of \$2.4 million in 2017
- Net decrease of \$3.1 million in expense relating to changes in fair value and impairment of our equity holdings and warrants in Bone Biologics common stock
- Partially offset by an increase of \$5.6 million associated with an other-than-temporary impairment on the eNeura debt security during the first quarter of 2017

Income Taxes

(U.S. Dollars, in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Income tax expense	\$ (115)	\$ 6,150	-101.9%	\$ 6,346	\$ 13,998	-54.7%
Effective tax rate	8.7%	64.8%	-56.1%	56.2%	70.8%	-14.6%

Three months ended September 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
- Decrease in the U.S. statutory rate from 35% to 21%
- Partially offset by the impairment of our investment in Bone Biologics, for which there is no tax benefit
- Further offset by increased financial expenses not deductible for tax purposes

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

- The mix of earnings among tax jurisdictions
- Impairment of our investment in Bone Biologics, for which there is no tax benefit
- Certain financial expenses not deductible for tax purposes

Nine months ended September 30, 2018 compared to 2017

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

- Decrease in pre-tax earnings
- Decrease in the U.S. statutory tax rate from 35% to 21%
- Partially offset by the impairment of our investment in Bone Biologics, for which there is no tax benefit
- Further offset by financial expenses not deductible for tax purposes

The primary factors affecting our effective tax rate for the nine months ended September 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
- Impairment of our investment in Bone Biologics, for which there is no tax benefit
- Certain financial expenses not deductible for tax purposes

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at September 30, 2018, totaled \$56.2 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.

Nine Months Ended September 30,				
(U.S. Dollars, in thousands)	2018	2017	Change	
Net cash from operating activities	\$ 28,829	\$ 9,125	\$	19,704
Net cash from investing activities	(55,921)	(12,816)		(43,105)
Net cash from financing activities	2,988	2,598		390
Effect of exchange rate changes on cash	(811)	1,077		(1,888)
Net change in cash, cash equivalents and restricted cash	\$ (24,915)	\$ (16)	\$	(24,899)

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.

Nine Months Ended September 30,				
(U.S. Dollars, in thousands)	2018	2017	Change	
Net cash from operating activities	\$ 28,829	\$ 9,125	\$	19,704
Capital expenditures	(10,724)	(13,290)		2,566
Free cash flow	\$ 18,105	\$ (4,165)	\$	22,270

Operating Activities

Cash flows from operating activities increased \$19.7 million

- Increase in net income of \$0.3 million
- Net decrease of \$3.7 million for non-cash gains and losses, largely related to changes in deferred income taxes, our other-than-temporary impairment on the eNeura debt security in the first quarter of 2017, share-based compensation expense, and impairment of the Company's investments in Bone Biologics in 2018
- Net increase of \$23.2 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, and changes in accounts receivable

Two of our primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 61 days at September 30, 2018 compared to 53 days at September 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 September 30, 2018 and 2017.

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

In November 2016, the Financial Accounting Standards Board (“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 an increase in net cash from operating activities of \$2.5 million for the nine months ended September 30, 2018 and a decrease in net cash from operating activities of \$14.4 million for the nine months ended September 30, 2017.

Investing Activities

Cash flows from investing activities decreased \$43.1 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 \$0.9 million associated with the acquisition of certain intangible assets in transactions with former distributors during the first and third quarters of 2018
- Decrease of \$0.5 million due to our additional investment in Bone Biologics 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 \$2.6 million

Financing Activities

Cash flows from financing activities increased \$0.4 million

- Increase in net proceeds of \$0.9 million from the issuance of common shares
- Partially offset by a decrease in other financing cash flows of \$0.5 million

Credit Facilities

On July 31, 2018, the Company amended and restated its previous Credit Agreement with JPMorgan Chase Bank, N.A. (“JPMorgan”), the Administrative Agent, and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement (“Amended Credit Agreement”). The Amended Credit Agreement is substantially the same as the previous 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 if the FDA grants approval of Spinal Kinetics’ M6-C artificial cervical 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. The fair value of the contingent consideration arrangement as of September 30, 2018 was \$28.2 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. Approximately \$13.6 million of this liability is included within other current liabilities and \$14.6 million is included within other long-term liabilities. For additional discussion of this matter, see Note 2 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Off-balance Sheet Arrangements

As of September 30, 2018, 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, 2017, except as related to our acquisition of Spinal Kinetics. As part of the acquisition, we assumed the contractual obligations relating to Spinal Kinetics' existing lease arrangements, which in the aggregate amount to future obligations totaling approximately \$3.6 million as of September 30, 2018.

Critical Accounting Estimates

Our discussion of operating results is based upon the condensed consolidated financial statements and accompanying notes. The preparation of these statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Our critical accounting estimates are detailed in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017.

Significant changes to our critical accounting estimates as a result of adopting ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606) are discussed below. Other than the changes to our critical accounting policies for revenue recognition, allowance for doubtful accounts, and contractual allowances as a result of the adoption of Topic 606, there have been no changes to our critical accounting estimates.

Revenue Recognition

The process for recognizing revenue involves significant assumptions and judgments for certain of our revenue streams. Revenue recognition policies are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, non-GAAP net margin, operating income, and net income.

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

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products, we recognize revenue 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.

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

Orthofix Extremities and Spinal Implants 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 our internal and external fixation products, generally representing hospital customers. Commercial revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital.

Stocking distributors purchase our products and then re-sell them directly to customers, such as hospitals. For revenue derived from stocking distributor agreements, prior to the adoption of Topic 606, i.e. for all periods presented prior to January 1, 2018, we recognized revenue once the product was delivered to the end customer (the "sell-through method"). Because we did not have reliable information about when our distributors sold the product through to end customers, we used cash collection from distributors as a basis for revenue recognition under the sell-through method. Additionally, when we sold to these distributors, we considered whether to match the related cost of sales expense with revenue or to recognize expense upon shipment. In making this assessment, we considered the financial viability of our 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 distributors. In instances where the distributor was determined to be financially viable, we deferred the costs of sales until the revenue was recognized.

Subsequent to the adoption of Topic 606, effective January 1, 2018, for revenue derived from stocking distributor arrangements, we recognize revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price is estimated based upon our historical collection experience with the stocking distributor. To derive this estimate, we analyze 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, which is when the Company's performance obligation has been satisfied.

Biologics revenue is largely attributable to the U.S. and is primarily related to a collaborative arrangement with MTF. We have exclusive global marketing rights and receive marketing fees from MTF based on products distributed by MTF. MTF is considered the principal in these arrangements; therefore, we recognize these marketing service fees on a net basis upon shipment of the product to the customer.

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collections, write-offs, and payor reimbursement experience are integral parts of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. 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. Our estimates are periodically tested against actual collection experience. Our allowance for doubtful accounts and estimation of contractual allowances are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, net margin, operating income, net income, and trade accounts receivable.

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 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. In the first quarter of 2018, we adopted ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. We adopted this accounting standard using a retrospective transition approach, which resulted in an increase in net cash from operating activities of \$2.5 million for the nine months ended September 30, 2018 and a decrease in net cash from operating activities of \$14.4 million for the nine months ended September 30, 2017.

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, 2017.

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 September 30, 2018. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2018.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, known to the President and Chief Executive Officer or the Chief Financial Officer that occurred for the quarterly period covered by this report that has materially affected, or is 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, 2017.

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

We have not made any repurchases of our common stock during the third quarter of 2018.

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

- 3.1 [Orthofix Medical Inc. Certificate of Incorporation \(filed as an exhibit to the Company's Current Report on Form 8-K filed July 31, 2018 and incorporated herein by reference\).](#)
- 3.2 [Orthofix Medical Inc. Bylaws \(filed as an exhibit to the Company's Current Report on Form 8-K filed July 31, 2018 and incorporated herein by reference\).](#)
- 4.1 [Form of Stock Certificate \(filed as an exhibit to the Company's Current Report on Form 8-K filed July 31, 2018 and incorporated herein by reference\).](#)
- 10.1 [Amended and Restated 2012 Long-Term Incentive Plan \(filed as an exhibit to the Company's Current Report on Form 8-K filed July 17, 2018 and incorporated herein by reference\).](#)
- 10.2 [Amendment No. 1 to Second Amended and Restated Stock Purchase Plan \(filed as an exhibit to the Company's Current Report on Form 8-K filed July 17, 2018 and incorporated herein by reference\).](#)
- 10.3 [First Amended and Restated Credit Agreement, dated as of July 31, 2018, among Orthofix Holdings, Inc., Victory Medical Limited, Orthofix International B.V., Orthofix Medical Inc. and certain subsidiaries of Orthofix Medical Inc. as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase Bank, N.A., as administrative agent \(filed as an exhibit to the Company's current report on Form 8-K filed August 6, 2018 and incorporated herein by reference\).](#)
- 10.4 [Amended and Restated Employment Contract, dated July 31, 2018 between Orthofix AG and Davide Bianchi \(filed as an exhibit to the Company's current report on Form 8-K filed on August 6, 2018 and incorporated herein by reference\).](#)
- 31.1* [Rule 13a-14\(a\)/15d-14\(a\) Certification of Chief Executive Officer.](#)
- 31.2* [Rule 13a-14\(a\)/15d-14\(a\) Certification of Chief Financial Officer.](#)
- 32.1* [Section 1350 Certifications of each of the Chief Executive Officer and Chief Financial Officer.](#)
- 101* The following materials from this Form 10-Q, formatted in Extensible Business Reporting Language ("XBRL"): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX MEDICAL INC.

Date: October 29, 2018

By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: October 29, 2018

By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer

CERTIFICATION

I, Bradley R. Mason, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2018, of Orthofix Medical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has material affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: October 29, 2018

By: /s/ BRADLEY R. MASON

Name: Bradley R. Mason

Title: President and Chief Executive Officer

CERTIFICATION

I, Doug Rice, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2018, of Orthofix Medical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: October 29, 2018

By: /s/ DOUG RICE

Name: Doug Rice

Title: Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Orthofix Medical Inc. ("Orthofix") on Form 10-Q for the quarterly period ended September 30, 2018, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, Bradley R. Mason, Chief Executive Officer and President of Orthofix, and Doug Rice, Chief Financial Officer, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Orthofix.

Dated: October 29, 2018

/s/ BRADLEY R. MASON

Name: Bradley R. Mason

Title: President and Chief Executive Officer

Dated: October 29, 2018

/s/ DOUG RICE

Name: Doug Rice

Title: Chief Financial Officer