

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2019

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 August 2, 2019, 19,031,280 shares of common stock were issued and outstanding.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.10 par value per share	OFIX	Nasdaq Global Select Market

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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, 2018 (the “2018 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 2018 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

	June 30, 2019	December 31, 2018
(U.S. Dollars, in thousands, except share data)	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 52,143	\$ 69,623
Restricted cash	—	2,566
Trade accounts receivable, net of allowances of \$4,205 and \$7,463, respectively	80,591	77,747
Inventories	79,141	76,847
Prepaid expenses and other current assets	20,954	17,856
Total current assets	232,829	244,639
Property, plant and equipment, net	64,402	42,835
Intangible assets, net	55,628	51,897
Goodwill	71,177	72,401
Deferred income taxes	37,566	33,228
Other long-term assets	27,204	21,641
Total assets	\$ 488,806	\$ 466,641
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	\$ 19,523	\$ 17,989
Current portion of finance lease liability	301	—
Other current liabilities	48,161	67,919
Total current liabilities	67,985	85,908
Long-term portion of finance lease liability	20,847	—
Other long-term liabilities	52,180	45,336
Total liabilities	141,012	131,244
Contingencies (Note 9)		
Shareholders' equity		
Common shares \$0.10 par value; 50,000,000 shares authorized; 18,831,581 and 18,579,688 issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1,883	1,858
Additional paid-in capital	257,888	243,165
Retained earnings	86,561	87,078
Accumulated other comprehensive income	1,462	3,296
Total shareholders' equity	347,794	335,397
Total liabilities and shareholders' equity	\$ 488,806	\$ 466,641

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)

	Three Months Ended June 30,		Six Months Ended June 30,	
(Unaudited, U.S. Dollars, in thousands, except share and per share data)	2019	2018	2019	2018
Net sales	\$ 115,850	\$ 111,547	\$ 224,962	\$ 220,256
Cost of sales	25,812	22,835	49,520	46,982
Gross profit	90,038	88,712	175,442	173,274
Sales and marketing	56,864	51,529	110,558	101,797
General and administrative	21,935	21,958	42,407	41,382
Research and development	8,980	7,891	18,209	14,828
Acquisition-related amortization and remeasurement (Note 13)	1,808	1,419	8,265	1,482
Operating income (loss)	451	5,915	(3,997)	13,785
Interest income (expense), net	457	(251)	200	(434)
Other expense, net	(236)	(3,643)	(640)	(731)
Income (loss) before income taxes	672	2,021	(4,437)	12,620
Income tax benefit (expense)	(1,219)	(1,096)	4,787	(6,469)
Net income (loss)	\$ (547)	\$ 925	\$ 350	\$ 6,151
Net income (loss) per common share:				
Basic	\$ (0.03)	\$ 0.05	\$ 0.02	\$ 0.33
Diluted	(0.03)	0.05	0.02	0.32
Weighted average number of common shares:				
Basic	18,834,886	18,413,756	18,790,612	18,409,331
Diluted	18,834,886	18,835,560	19,179,057	18,811,356
Other comprehensive income (loss), before tax				
Unrealized gain (loss) on debt security	—	1,960	(2,593)	1,960
Reclassification adjustment for amortization of historical unrealized gains on debt security	(689)	—	(689)	—
Currency translation adjustment	147	(1,175)	(302)	(478)
Other comprehensive income (loss) before tax	(542)	785	(3,584)	1,482
Income tax related to other comprehensive income (loss)	171	(432)	812	(432)
Other comprehensive income (loss), net of tax	(371)	353	(2,772)	1,050
Comprehensive income (loss)	\$ (918)	\$ 1,278	\$ (2,422)	\$ 7,201

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

ORTHOFIX MEDICAL INC.
Condensed Consolidated Statements of Changes in Shareholders' Equity

(Unaudited, U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders' Equity
At December 31, 2018	18,579,688	\$ 1,858	\$ 243,165	\$ 87,078	\$ 3,296	\$ 335,397
Cumulative effect adjustment from adoption of ASU 2016-02	—	—	—	71	—	71
Cumulative effect adjustment from adoption of ASU 2018-02	—	—	—	(938)	938	—
Net income	—	—	—	897	—	897
Other comprehensive loss, net of tax	—	—	—	—	(2,401)	(2,401)
Share-based compensation	—	—	5,685	—	—	5,685
Common shares issued, net	211,081	21	4,012	—	—	4,033
At March 31, 2019	18,790,769	\$ 1,879	\$ 252,862	\$ 87,108	\$ 1,833	\$ 343,682
Net loss	—	—	—	(547)	—	(547)
Other comprehensive loss, net of tax	—	—	—	—	(371)	(371)
Share-based compensation	—	—	5,849	—	—	5,849
Common shares issued, net	40,812	4	(823)	—	—	(819)
At June 30, 2019	18,831,581	\$ 1,883	\$ 257,888	\$ 86,561	\$ 1,462	\$ 347,794

(Unaudited, U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders' Equity
At December 31, 2017	18,278,833	\$ 1,828	\$ 220,591	\$ 70,402	\$ 3,787	\$ 296,608
Cumulative effect adjustment from adoption of ASU 2014-09	—	—	—	4,761	—	4,761
Cumulative effect adjustment from adoption of ASU 2016-16	—	—	—	(1,896)	—	(1,896)
Net income	—	—	—	5,226	—	5,226
Other comprehensive income, net of tax	—	—	—	—	697	697
Share-based compensation	—	—	3,916	—	—	3,916
Common shares issued, net	126,511	13	3,849	—	—	3,862
At March 31, 2018	18,405,344	\$ 1,841	\$ 228,356	\$ 78,493	\$ 4,484	\$ 313,174
Net income	—	—	—	925	—	925
Other comprehensive income, net of tax	—	—	—	—	353	353
Share-based compensation	—	—	5,215	—	—	5,215
Common shares issued, net	80,444	8	171	—	—	179
At June 30, 2018	18,485,788	\$ 1,849	\$ 233,742	\$ 79,418	\$ 4,837	\$ 319,846

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

ORTHOFIX MEDICAL INC.
Condensed Consolidated Statements of Cash Flows

	Six Months Ended June 30,	
(Unaudited, U.S. Dollars, in thousands)	2019	2018
Cash flows from operating activities		
Net income	\$ 350	\$ 6,151
Adjustments to reconcile net income to net cash from operating activities		
Depreciation and amortization	11,905	8,923
Amortization of operating lease assets, debt costs and other assets	1,750	592
Provision for doubtful accounts	638	(360)
Deferred income taxes	(2,316)	724
Share-based compensation	11,534	9,131
Interest and gain on valuation of investment securities	(1,023)	(1,399)
Change in fair value of contingent consideration	5,870	1,109
Other	477	847
Changes in operating assets and liabilities, net of effects of acquisitions		
Accounts receivable	(3,535)	(363)
Inventories	(2,389)	5,251
Prepaid expenses and other current assets	(3,277)	71
Accounts payable	1,626	(3,847)
Other current liabilities	(8,138)	(14,612)
Payment of contingent consideration	(1,340)	—
Other long-term assets and liabilities	(3,788)	814
Net cash from operating activities	8,344	13,032
Cash flows from investing activities		
Acquisition of business, net of cash acquired	—	(43,749)
Capital expenditures for property, plant and equipment	(9,595)	(5,782)
Capital expenditures for intangible assets	(743)	(870)
Asset acquisitions and other investments	(6,400)	(1,148)
Net cash from investing activities	(16,738)	(51,549)
Cash flows from financing activities		
Proceeds from issuance of common shares	6,523	5,416
Payments related to withholdings for share-based compensation	(3,309)	(1,375)
Payment of contingent consideration	(13,660)	—
Payments related to finance lease obligation	(188)	—
Other financing activities	(947)	(356)
Net cash from financing activities	(11,581)	3,685
Effect of exchange rate changes on cash	(71)	(639)
Net change in cash, cash equivalents, and restricted cash	(20,046)	(35,471)
Cash, cash equivalents, and restricted cash at the beginning of period	72,189	81,157
Cash, cash equivalents, and restricted cash at the end of period	\$ 52,143	\$ 45,686
Components of cash, cash equivalents and restricted cash at the end of period		
Cash and cash equivalents	\$ 52,143	\$ 45,686
Restricted cash	—	—
Cash, cash equivalents, and restricted cash at the end of period	\$ 52,143	\$ 45,686
Supplemental Disclosure of Cash Flow Information:		
Noncash investing activities:		
Purchase of intangible assets	\$ —	\$ 1,181
Contingent consideration recognized at acquisition date	—	25,491

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

ORTHOFIX MEDICAL INC.
Notes to the Unaudited Condensed Consolidated Financial Statements

1. Business and basis of presentation

Orthofix Medical Inc., 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 two reporting segments: Global Spine and Global Extremities.

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, 2018. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2019.

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; allowance for doubtful accounts; inventories; valuation of intangible assets; goodwill; fair value measurements, including contingent consideration; litigation and contingent liabilities; tax matters; and share-based compensation. Actual results could differ from these estimates.

Prior period reclassifications

Certain amortization expense related to intangible assets previously reported in general and administrative expenses have been reclassified to acquisition-related amortization and remeasurement based on use of the underlying intangible asset. This reclassification resulted in decreases to general and administrative expenses of \$0.3 million and \$0.4 million for the three and six months ended June 30, 2018, respectively, and increases in acquisition related amortization and remeasurement expense of \$0.3 million and \$0.4 million for the three and six months ended June 30, 2018, respectively.

Additionally, as disclosed in the Company’s Form 10-K for the year ended December 31, 2018, the Company reclassified \$1.1 million of previously reported expense during the second quarter of 2018 related to changes in fair value of contingent consideration from other expense, net, to acquisition-related amortization and remeasurement to conform to current period presentation.

Change in Reporting Segments

The Company has changed its reportable business segments beginning with the first quarter of 2019, to align with changes in how the Company manages its business, reviews operating performance and allocates resources. The Company now reports results under two reportable segments: Global Spine and Global Extremities, and measures operating performance of these two reportable segments based on EBITDA. For additional discussion regarding segments, see Note 12.

2. Recently adopted accounting standards and recently issued accounting pronouncements

Adoption of ASU 2016-02, Leases (Topic 842)

In February 2016 the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, which changes how lessees account for leases. For most leases, a liability will be recorded on the balance sheet based on the present value of future lease obligations with a corresponding right-of-use asset. For leases classified as operating leases, the Company will recognize lease costs on a straight-line basis based on the combined amortization of the lease obligation and the right-of-use asset. Other leases will be accounted for as finance leases similar to capital leases under the previous accounting standard. Effective January 1, 2019, the Company adopted ASU 2016-02 using a modified retrospective approach. Upon adoption, the Company elected a package of practical expedients permitted within the new standard. The practical expedients adopted allow the Company to carry forward its historical lease classification and to not separate and allocate the consideration paid between lease and non-lease components included within a contract. The Company also adopted an optional transition method that waives the requirement to apply the ASU to the comparative periods presented within the financial statements in the year of adoption. Therefore, results for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts are not adjusted and

continue to be reported in accordance with the Company's historic accounting policies under Topic 840. See Note 5 for additional discussion of the Company's adoption of Topic 842 and its lease accounting policies.

Adoption of ASU 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

In February 2018, the FASB issued ASU 2018-02, which 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"). The Company adopted this guidance effective January 1, 2019, which resulted in an increase to accumulated other comprehensive income and a decrease in retained earnings of \$0.9 million.

Other recently adopted 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 Company adopted Release No. 33-10532 during the first quarter of 2019, which resulted in changes in shareholders' equity presented within the Condensed Consolidated Statements of Changes in Shareholders' Equity.

Recently issued accounting pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Financial Instruments - Credit Losses (ASU 2016-13), and subsequent amendments	Requires that credit losses for certain types of financial instruments be estimated based on expected losses and also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. Applied using a modified retrospective approach, with early adoption permitted.	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
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.
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.

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
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.

3. Acquisitions

Acquisition of Spinal Kinetics, Inc.

On April 30, 2018, the Company completed the acquisition of Spinal Kinetics Inc. ("Spinal Kinetics"), a privately held developer and manufacturer of artificial cervical and lumbar discs for \$45.0 million in net cash, subject to certain adjustments, plus potential milestone payments of up to \$60.0 million in cash. The acquisition date fair value of the consideration transferred was \$76.6 million. The results of operations for Spinal Kinetics have been included in the Company's financial results since the acquisition date, April 30, 2018. For additional discussion regarding the valuation of the contingent consideration, see Note 7.

The following table summarizes the fair values of assets acquired and liabilities assumed at the acquisition date. During the first quarter of 2019, the Company finalized its valuation of assets acquired and liabilities assumed, which resulted in an adjustment between deferred income taxes and goodwill.

(U.S. Dollars, in thousands)	Preliminary Acquisition Date Fair Value as Previously Reported	Adjustments	Final Acquisition Date Fair Value	Assigned Useful Life
Assets acquired				
Cash and cash equivalents	\$ 6,785	\$ —	\$ 6,785	
Restricted cash	30	—	30	
Accounts receivable	1,705	—	1,705	
Inventories	8,175	—	8,175	
Prepaid expenses and other current assets	315	—	315	
Property, plant and equipment	2,285	—	2,285	
Other long-term assets	320	—	320	
Developed technology	12,400	—	12,400	10 years
In-process research and development ("IPR&D")	26,800	—	26,800	10 years
Tradename	100	—	100	2 years
Deferred income taxes	2,374	1,220	3,594	
Total identifiable assets acquired	\$ 61,289	\$ 1,220	\$ 62,509	
Liabilities assumed				
Accounts payable	\$ 351	\$ —	\$ 351	
Other current liabilities	2,873	(4)	2,869	
Other long-term liabilities	301	—	301	
Total liabilities assumed	\$ 3,525	\$ (4)	\$ 3,521	
Goodwill	18,836	(1,224)	17,612	
Total fair value of consideration transferred	\$ 76,600	\$ —	\$ 76,600	

On February 6, 2019, the Company obtained U.S. Food and Drug Administration (“FDA”) approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration and started amortizing IPR&D. The \$17.6 million of goodwill recognized was assigned to the Global Spine reporting segment.

The Company did not recognize any acquisition related costs during the three and six months ended June 30, 2019 and recorded \$1.5 million and \$3.0 million of acquisition related costs during the three and six months ended June 30, 2018. 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 net sales of \$3.2 million and \$2.3 million related to Spinal Kinetics for the three months ended June 30, 2019 and 2018, respectively, and net sales of \$6.4 million and \$2.3 million for the six months ended June 30, 2019 and 2018, respectively. Additionally, the Company’s results of operations included net losses of \$3.4 million and \$1.8 million related to Spinal Kinetics for the three months ended June 30, 2019 and 2018, respectively, and net losses of \$7.4 million and \$1.8 million for the six months ended June 30, 2019 and 2018, respectively.

The following table presents the unaudited pro forma results for the three and six months ended June 30, 2019 and 2018, which combines the historical results of operations of Orthofix and Spinal Kinetics as though the companies had been combined as of January 1, 2018. The unaudited pro forma information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at such time.

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net sales	\$ 115,850	\$ 115,129	\$ 224,962	\$ 227,584
Net income (loss)	(547)	597	350	5,457

Options Medical, LLC Asset Acquisition

On January 31, 2019, the Company acquired certain assets of Options Medical, LLC, (“Options Medical”) a medical device distributor based in Florida. Under the terms of the acquisition, the parties agreed to terminate an existing exclusive sales representative agreement, employees of Options Medical became employees of the Company and the Company acquired all customer lists and customer information related to the sale of the Company’s products. As consideration for the assets acquired, the Company paid \$6.4 million. Additionally, as an inducement to enter into employment with the Company, the Company provided 25,478 restricted stock units (“RSUs”), with a fair value of \$1.4 million, to the Options Medical founder. These RSUs will vest in one-third annual increments beginning on the first anniversary of the grant date and are contingent upon continued employment. The following table summarizes the fair values of assets acquired and liabilities assumed at the acquisition date.

(U.S. Dollars, in thousands)	Fair Value	Balance Sheet Classification	Assigned Useful Life
Assets acquired			
Operating lease assets	\$ 175	Other long-term assets	
Customer relationships	5,832	Intangible assets, net	10 years
Assembled workforce	568	Intangible assets, net	5 years
Total identifiable assets acquired	\$ 6,575		
Liabilities assumed			
Operating lease liability - short-term	\$ 69	Other current liabilities	
Operating lease liability - long-term	106	Other long-term liabilities	
Total liabilities assumed	175		
Total fair value of consideration transferred	\$ 6,400		

4. Inventories

Inventories were as follows:

(U.S. Dollars, in thousands)	June 30, 2019	December 31, 2018
Raw materials	\$ 7,752	\$ 8,463
Work-in-process	11,421	13,478
Finished products	59,968	54,906
Inventories	\$ 79,141	\$ 76,847

5. Leases

As discussed in Note 2, the Company adopted ASU No. 2016-02—*Leases (Topic 842)*, as of January 1, 2019, using the modified retrospective approach. Adoption of the new standard resulted in the recording of additional lease assets and lease liabilities of \$20.2 million and \$20.5 million, respectively, as of January 1, 2019. The difference between the additional lease assets and lease liabilities, net of the deferred tax impact and the elimination of historical prepaid or deferred rent, was recorded as an adjustment to retained earnings. The net impact of adoption to the Company's balance sheet as of January 1, 2019 is presented in the table below. The standard did not have a material impact to the Company's condensed consolidated statements of operations and comprehensive income (loss) or cash flows.

(U.S. Dollars, in thousands)	December 31, 2018	Impact of Adoption of ASC 842	January 1, 2019
Assets			
Current assets			
Cash, cash equivalents, and restricted cash	\$ 72,189	\$ —	\$ 72,189
Accounts receivable, net	77,747	—	77,747
Inventories	76,847	—	76,847
Prepaid expenses and other current assets	17,856	(15)	17,841
Total current assets	244,639	(15)	244,624
Property, plant, and equipment, net	42,835	—	42,835
Intangible assets, net and goodwill	124,298	—	124,298
Deferred income taxes	33,228	71	33,299
Other long-term assets	21,641	20,209	41,850
Total assets	\$ 466,641	\$ 20,265	\$ 486,906
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	\$ 17,989	\$ —	\$ 17,989
Other current liabilities	67,919	2,166	70,085
Total current liabilities	85,908	2,166	88,074
Other long-term liabilities	45,336	18,028	63,364
Total liabilities	\$ 131,244	\$ 20,194	\$ 151,438
Shareholders' equity			
Common shares	1,858	—	1,858
Additional paid-in capital	243,165	—	243,165
Retained earnings	87,078	71	87,149
Accumulated other comprehensive income	3,296	—	3,296
Total shareholders' equity	335,397	71	335,468
Total liabilities and shareholders' equity	\$ 466,641	\$ 20,265	\$ 486,906

The Company determines if an arrangement is a lease at inception. The Company's leases primarily relate to facilities, vehicles, and equipment. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company's incremental borrowing rate is used as a discount rate, based on the information available at the commencement date, in determining the present value of lease payments. Lease assets also include the impact of any prepayments made and are reduced by impact of any lease incentives.

The Company has made an accounting policy election for short-term leases, in that the Company will not recognize a lease liability or lease asset on the balance sheet for leases with a lease term of twelve months or less as of the commencement date. Rather, any short-term lease payments will be recognized as an expense on a straight-line basis over the lease term. The current period short-term lease expense reasonably reflects our short-term lease commitments.

The Company has made a policy election for all classifications of leases to combine lease and nonlease components and to account for them as a single lease component. Variable lease payments are excluded from the lease liability and recognized in the period in which the obligation is incurred. Additionally, lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option.

During the first quarter of 2019, the Company entered into an amendment for its corporate headquarters lease. As a result, the classification of this lease changed from an operating lease to a finance lease, resulting in an increase to both the lease liability and lease asset of approximately \$8.0 million.

A summary of the Company's lease portfolio as of June 30, 2019 is presented in the table below:

(U.S. Dollars, in thousands, except lease term and discount rate)	Classification	June 30, 2019
Assets		
Operating leases	Other long-term assets	\$ 6,353
Finance leases	Property, plant and equipment, net	20,695
Total lease assets		27,048
Liabilities		
Current		
Operating leases	Other current liabilities	1,816
Finance leases	Current portion of finance lease liability	301
Long-term		
Operating leases	Other long-term liabilities	4,609
Finance leases	Long-term portion of finance lease liability	20,847
Total lease liabilities		\$ 27,573
Weighted Average Remaining Lease Term		
Operating leases		4.5 years
Finance leases		21.2 years
Weighted Average Discount Rate		
Operating leases		2.46%
Finance leases		4.38%

The components of lease costs were as follows:

(U.S. Dollars, in thousands)	Three Months ended June 30, 2019	Six Months Ended June 30, 2019
Finance lease costs:		
Amortization of right-of-use assets	\$ 245	\$ 484
Interest on finance lease liabilities	231	454
Operating lease costs	540	1,080
Short-term lease costs	72	134
Variable lease costs	176	328
Total lease costs	\$ 1,264	\$ 2,480

Supplemental cash flow information related to leases was as follows:

(U.S. Dollars, in thousands)	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	\$ 2,055
Operating cash flows from finance leases	454
Financing cash flows from finance leases	188
Right-of-use assets obtained in exchange for lease obligations	
Operating leases	362
Finance leases	21,179

A summary of the Company's remaining lease liabilities as of June 30, 2019 is included below:

(U.S. Dollars, in thousands)	Operating Leases	Finance Leases
2019	\$ 977	\$ 642
2020	1,808	1,013
2021	1,593	1,414
2022	1,312	1,443
2023	256	1,471
Thereafter	803	27,207
Total undiscounted value of lease liabilities	\$ 6,749	\$ 33,190
Less: Interest	(324)	(12,042)
Present value of lease liabilities	\$ 6,425	\$ 21,148
Current portion of lease liabilities	1,816	301
Long-term portion of lease liabilities	4,609	20,847
Total lease liabilities	\$ 6,425	\$ 21,148

6. Long-term debt

As of June 30, 2019, the Company had no borrowings under its five year \$125 million secured revolving credit facility. In addition, the Company had no borrowings on its €5.5 million (\$6.3 million) available lines of credit in Italy as of June 30, 2019. The Company is in compliance with all required financial covenants as of June 30, 2019.

7. Fair value measurements

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

(U.S. Dollars, in thousands)	June 30, 2019				December 31, 2018
	Level 1	Level 2	Level 3	Total	Total
Assets					
Treasury securities	\$ 502	\$ —	\$ —	\$ 502	\$ 490
Bone Biologics equity warrants	—	—	—	—	—
Bone Biologics equity securities	—	219	—	219	219
eNeura debt security	—	—	—	—	17,820
eNeura warrant	—	—	491	491	—
Total	\$ 502	\$ 219	\$ 491	\$ 1,212	\$ 18,529
Liabilities					
Contingent consideration	\$ —	\$ —	\$ (19,430)	\$ (19,430)	\$ (28,560)
Deferred compensation plan	—	(1,314)	—	(1,314)	(1,275)
Total	\$ —	\$ (1,314)	\$ (19,430)	\$ (20,744)	\$ (29,835)

Bone Biologics 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 considered to have a fair value of zero. The equity securities are considered investments that do not have readily determinable fair values. As such, the Company measures these 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.

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Bone Biologics equity securities and warrants beginning balance	\$ 219	\$ 4,897	\$ 219	\$ 2,768
Impact of adoption of ASU 2016-01 recognized in other income (expense), net	—	—	—	1,629
Purchase of additional common stock	—	—	—	500
Fair value adjustments, expirations, and impairments recognized in other income (expense), net	—	(229)	—	(229)
Bone Biologics equity securities and warrants ending balance	\$ 219	\$ 4,668	\$ 219	\$ 4,668

eNeura Debt Security and Warrant

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 was originally set to mature on March 4, 2019. On March 1, 2019, the Company entered into an Amended and Restated Senior Secured Promissory Note with eNeura (the "Restructured Debt Security") to restructure the debt security, which extended the maturity date to the earlier of (i) March 4, 2022, (ii) the effective date of a change in control, or (iii) the effective date of an initial public offering by eNeura and which also eliminated the conversion feature included within the original note. As consideration for the extension, eNeura issued to the Company a Warrant to Purchase Common Stock (the "Warrant"), exercisable at \$0.01 per share over a ten year contractual term, for a number of shares equal to 10% of the sum of the outstanding principal and accrued interest on the Amended and Restated Debt Security as of March 1, 2019, divided by \$1.00 (subject to certain anti-dilution provisions).

Prior to the restructuring on March 1, 2019, the debt security was accounted for as an available for sale debt security at fair value and included within other long-term assets. The fair value was based upon significant unobservable inputs, including the use of a discounted cash flow model and assumptions regarding the expected payback period for the debt security, requiring the Company to develop its own assumptions; therefore, the Company had categorized this asset as a Level 3 financial asset. Subsequent to the restructuring, the debt security is no longer classified as an available for sale debt security, but rather as a held to maturity debt security. As a result, the amounts included in accumulated other comprehensive income related to this debt security are now being amortized to interest

income over the extended term of the Restructured Debt Security. For additional discussion regarding the Restructured Debt Security, see Note 8.

The Warrant is recorded at fair value and included in other long-term assets. The fair value of the Warrant is based on significant unobservable inputs, including the use of a discounted cash flow model and an option-pricing model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. As of June 30, 2019, the estimated fair value of the Warrant was \$0.5 million. The Warrant is considered an investment that does not have a readily determinable fair value. As such, the Company measures the Warrant 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 following table provides a reconciliation of the beginning and ending balances for the eNeura debt security and Warrant measured and reflected in the condensed consolidated balance sheets at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2019	2018
eNeura debt security and Warrant at January 1	\$ 17,820	\$ 16,050
Gains or losses recorded for the period		
Recognized in other comprehensive income (loss)	(2,593)	1,960
Change in classification of debt security to held to maturity	(15,227)	—
Issuance of warrant as consideration for extension	491	—
eNeura debt security and Warrant at June 30	\$ 491	\$ 18,010

Contingent Consideration

The contingent consideration at the acquisition date of Spinal Kinetics consisted of potential future milestone payments of up to \$60.0 million in cash. The milestone payments included (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.

On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc. This approval triggered the Company's payment obligation of \$15.0 million for the achievement of the FDA Milestone and such obligation was paid on February 14, 2019. The fair value of the remaining contingent consideration was \$19.4 million as of June 30, 2019; however, the actual amount ultimately paid could be higher or lower than the fair value of the remaining contingent consideration. The remaining liability attributable to the revenue-based milestones is included within other long-term liabilities. Any changes in fair value are recorded as an operating expense and included within acquisition-related amortization and remeasurement.

The Company estimated the fair value of the remaining 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)	2019	2018
Contingent consideration at January 1	\$ 28,560	\$ —
Acquisition date fair value	—	25,491
Increase in fair value recognized in acquisition-related amortization and remeasurement	5,870	1,109
Payment made	(15,000)	—
Contingent consideration at June 30	\$ 19,430	\$ 26,600

8. Investments

As a result of the restructuring of the eNeura debt security discussed in Note 7, the eNeura debt security was reclassified from an available for sale debt security to a held to maturity debt security at its fair value on the date of the restructuring. The unrealized gain included in accumulated other comprehensive income at the restructuring date continues to be included in accumulated other comprehensive income and is now being amortized to interest income over the remaining life of the Restructured Debt Security. The Restructured Debt Security will be evaluated for impairment based on management's estimate of future cash collections discounted using the debt security's original effective interest rate of 8%. Management's estimate of future cash flows involves significant judgment regarding the timing, expected events, and amount of future cash collections. Decreases in management's estimate of future cash collections could result in an other than temporary impairment. As of June 30, 2019, the Company's amortized cost basis in the Restructured Note was \$15.1 million, which also represents its carrying value, compared to an estimated fair value of \$16.0 million and an unpaid principal balance of \$15.0 million. During the three and six months ended June 30, 2019, the Company recognized \$0.2 and \$0.3 million in interest income related to the eNeura debt security. The Company did not recognize any interest income during the three and six months ended June 30, 2018.

9. 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.

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 recorded expense of \$0.3 million and \$0.3 million for the three months ended June 30, 2019 and 2018, respectively and \$0.7 million and \$0.5 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the Company has accrued \$4.3 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 inspected the offices of more than 30 companies, including the Company'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 the Company's (and other companies') local bank accounts resulting in the freezing of approximately \$2.5 million of the Company's cash, which the Company reclassified to restricted cash. On April 3, 2019, the Company's appeal regarding the freezing of its local bank accounts was heard by the Brazil Federal Court of Appeals of Rio de Janeiro, in which the Court ordered the unfreezing of the Company's cash. The cash was then returned without any restrictions in April 2019. As such, this balance has been reclassified to cash and cash equivalents as of June 30, 2019.

10. 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, 2018	\$ (2,386)	\$ 5,682	\$ 3,296
Cumulative effect adjustment from adoption of ASU 2018-02	—	938	938
Other comprehensive loss	(302)	(2,593)	(2,895)
Income taxes	—	641	641
Reclassification adjustment to:			
Interest income (expense), net	—	(689)	(689)
Income taxes	—	171	171
Balance at June 30, 2019	\$ (2,688)	\$ 4,150	\$ 1,462

11. Revenue recognition and accounts receivable

Revenue Recognition

The Company has two reporting segments, which consist of Global Spine and Global Extremities. Within the Global Spine reporting segment there are three product categories: Bone Growth Therapies, Spinal Implants and Biologics.

The tables below present net sales by major product category by reporting segment:

Three Months Ended June 30,			
(U.S. Dollars, in thousands)	2019	2018	Change
Bone Growth Therapies	\$ 50,109	\$ 48,211	3.9%
Spinal Implants	23,226	23,880	-2.7%
Biologics	16,744	14,668	14.2%
Global Spine	90,079	86,759	3.8%
Global Extremities	25,771	24,788	4.0%
Net sales	\$ 115,850	\$ 111,547	3.9%

Six Months Ended June 30,			
(U.S. Dollars, in thousands)	2019	2018	Change
Bone Growth Therapies	\$ 97,392	\$ 94,374	3.2%
Spinal Implants	46,129	44,587	3.5%
Biologics	32,476	29,003	12.0%
Global Spine	175,997	167,964	4.8%
Global Extremities	48,965	52,292	-6.4%
Net sales	\$ 224,962	\$ 220,256	2.1%

Product Sales and Marketing Service Fees

The table below presents net sales, which includes product sales and marketing service fees, for the three and six months ended June 30, 2019 and 2018.

	Three Months Ended June 30,		Six Months Ended June 30,	
(U.S. Dollars, in thousands)	2019	2018	2019	2018
Product sales	\$ 99,865	\$ 97,453	\$ 193,799	\$ 192,342
Marketing service fees	15,985	14,094	31,163	27,914
Net sales	\$ 115,850	\$ 111,547	\$ 224,962	\$ 220,256

Product sales primarily consist of the sale of bone growth therapy devices and internal and external fixation products. Marketing service fees are received from MTF Biologics based on total sales of biologics tissues and relate solely to the Global Spine 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.

Puerto Rico Settlement

In June 2019, the Company received a payment of \$1.4 million from the Administration of Medical Services of Puerto Rico, a government-owned corporation, in settlement of approximately \$2.5 million of outstanding accounts receivable. This \$2.5 million of outstanding accounts receivable had previously been fully reserved between the Company's allowances for doubtful accounts and contractual allowances. As a result of this settlement, and in accordance with the Company's policy, the Company recorded the resulting adjustment to contractual allowances of \$0.4 million within net sales and the recovery of the allowance for doubtful accounts as a credit to bad debt expense of \$1.0 million.

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 or other current assets, dependent upon the original term of the related agreement, and totaled \$3.9 million and \$1.9 million as of June 30, 2019, and December 31, 2018, respectively.

12. Business segment information

During the first quarter of 2019, the Company changed its reporting segments from four reporting segments, previously reported as Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities, to two reporting segments: Global Spine and Global Extremities. Additionally, the Company changed the performance measure used to evaluate segment performance from Non-GAAP net margin to earnings before interest income (expense), net, income taxes, depreciation and amortization ("EBITDA"). These changes were made to align how the chief operating decision maker manages the business, reviews operating performance and allocates resources. The Company has revised its segment reporting to represent how the business is now managed and restated prior periods to conform to the current segment presentation. Corporate activities are comprised of the operating expenses and activities of the Company not necessarily identifiable within the two reporting segments, such as human resources, finance, legal, and information technology functions.

As part of the change in reporting segments, the Company performed a quantitative assessment of goodwill immediately prior to and subsequently following the change in reporting segments. The analysis did not result in an impairment. In addition, the net carrying value of goodwill that was previously reported under the prior reporting segments (i) Bone Growth Therapies (ii) Spinal Implants and (iii) Biologics have been consolidated and are included within the Global Spine reporting segment as of June 30, 2019.

As mentioned above, the primary metric used in managing the Company is EBITDA. The table below presents EBITDA by reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Global Spine	\$ 16,523	\$ 19,030	\$ 27,098	\$ 37,855
Global Extremities	2,750	488	2,577	3,816
Corporate	(12,880)	(12,692)	(22,407)	(19,694)
Total EBITDA	\$ 6,393	\$ 6,826	\$ 7,268	\$ 21,977
Depreciation and amortization	(6,178)	(4,554)	(11,905)	(8,923)
Interest income (expense), net	457	(251)	200	(434)
Income (loss) before income taxes	\$ 672	\$ 2,021	\$ (4,437)	\$ 12,620

Geographical information

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

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<i>Global Spine</i>				
U.S.	\$ 84,601	\$ 81,722	\$ 164,127	\$ 159,760
International	5,478	5,037	11,870	8,204
Total Global Spine	90,079	86,759	175,997	167,964
<i>Global Extremities</i>				
U.S.	6,844	7,023	13,442	13,939
International	18,927	17,765	35,523	38,353
Total Global Extremities	25,771	24,788	48,965	52,292
<i>Consolidated</i>				
U.S.	91,445	88,745	177,569	173,699
International	24,405	22,802	47,393	46,557
Net sales	\$ 115,850	\$ 111,547	\$ 224,962	\$ 220,256

13. Acquisition-related amortization and remeasurement

Acquisition-related amortization and remeasurement consists of amortization related to intangible assets acquired through business combinations or asset acquisitions and the remeasurement of any related contingent consideration arrangement. Components of acquisition-related amortization and remeasurement for the three months and six months ended June 30, 2019 and 2018, respectively, are as follows:

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Changes in fair value of contingent consideration	\$ 470	\$ 1,109	\$ 5,870	\$ 1,109
Amortization of acquired intangibles	1,338	310	2,395	373
Total	\$ 1,808	\$ 1,419	\$ 8,265	\$ 1,482

14. 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of sales	\$ 180	\$ 132	\$ 367	\$ 257
Sales and marketing	692	473	1,302	922
General and administrative	4,564	4,249	9,128	7,294
Research and development	413	361	737	658
Total	\$ 5,849	\$ 5,215	\$ 11,534	\$ 9,131

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock options	\$ 926	\$ 1,241	\$ 3,038	\$ 1,863
Time-based restricted stock awards and units	2,951	1,789	4,657	3,236
Performance-based restricted stock awards and units	—	270	—	759
Market-based restricted stock units	1,576	1,604	2,923	2,557
Stock purchase plan	396	311	916	716
Total	\$ 5,849	\$ 5,215	\$ 11,534	\$ 9,131

During the three months ended June 30, 2019 and 2018, the Company issued 40,812 and 80,444 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards and units. During the six months ended June 30, 2019 and 2018, the Company issued 251,893 and 206,955 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards and units.

On August 5, the Company entered into an employment agreement with its new President of Global Spine and awarded restricted stock units and stock options valued at approximately \$1.5 million as inducement grants.

Share-Based Compensation Modifications

During the first quarter of 2019, the Company entered into a Transition and Retirement Agreement (the “Retirement Agreement”) with the Company’s President and Chief Executive Officer. As part of the Retirement Agreement, certain time-based stock options and restricted stock awards were modified to accelerate the vesting to the retirement date. In addition, stock options were modified to extend the post-termination exercise period from 18 months under a standard qualified retirement to up to four years, dependent upon the remaining contractual term of the options. The Company recognized approximately \$1.5 million and \$3.7 million in share-based compensation expense during the three and six months ended June 30, 2019, related to the Retirement Agreement, which was charged to general and administrative expense in the condensed consolidated statements of operations and comprehensive income (loss).

15. Income taxes

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

For the three months ended June 30, 2019 and 2018, the effective tax rate was 181.4% and 54.2%, respectively. For the six months ended June 30, 2019 and 2018, the effective tax rate was 107.9% and 51.3%, respectively. The primary factors affecting the Company’s effective tax rate for the three and six months ended June 30, 2019, were increased limitation of the deductibility of executive compensation, financial expenses not deductible for tax purposes, and benefits related to effective settlement of the 2015 federal tax examination and statute expirations.

During the first quarter of 2019, the Internal Revenue Service concluded an examination of the Company’s federal income tax return for 2015, which resulted in a benefit of \$1.8 million. 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 \$13.0 million to \$13.4 million as audits close and statutes expire.

16. Earnings per share ("EPS")

The Company uses the two-class method of computing basic EPS due to the existence of non-vested restricted stock awards with nonforfeitable rights to dividends or dividend equivalents (referred to as participating securities). For the three and six months ended June 30, 2019 and 2018, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Weighted average common shares-basic	18,834,886	18,413,756	18,790,612	18,409,331
Effect of dilutive securities				
Unexercised stock options and stock purchase plan	—	327,171	259,967	318,047
Unvested restricted stock awards and units	—	94,633	128,478	83,978
Weighted average common shares-diluted	18,834,886	18,835,560	19,179,057	18,811,356

There were 1,987,907 and 413,296 weighted average outstanding stock options and restricted stock awards and units not included in the diluted EPS computation for the three months ended June 30, 2019 and 2018, respectively, and 483,731 and 259,470 weighted average outstanding stock options and restricted stock awards and units not included in the diluted EPS computation for the six months ended June 30, 2019 and 2018, respectively, because inclusion of these awards was anti-dilutive 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 (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 two reporting segments: Global Spine and Global Extremities. Our products are widely distributed by our sales representatives and distributors.

Notable highlights and achievements in the second quarter of 2019 include the following:

- Net sales were \$115.9 million, an increase of 3.9% on a reported basis and 5.0% on a constant currency basis
- Increase in Biologics net sales of 14.2% compared to the prior year period, as we believe we now have the #1 market-share position within the U.S. Cellular Allograft segment per SmartTRAK following strong performance in 2019
- Net loss was \$0.5 million, a decrease of \$1.5 million compared to the prior year period
- Decrease in earnings before interest, income taxes, depreciation, and amortization ("EBITDA") of \$0.4 million, or 6.3%

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 June 30,		Six Months Ended June 30,	
	2019 (%)	2018 (%)	2019 (%)	2018 (%)
Net sales	100.0	100.0	100.0	100.0
Cost of sales	22.3	20.5	22.0	21.3
Gross profit	77.7	79.5	78.0	78.7
Sales and marketing	49.1	46.2	49.1	46.2
General and administrative	18.9	19.7	18.9	18.8
Research and development	7.8	7.0	8.1	6.7
Acquisition-related amortization and remeasurement	1.5	1.3	3.7	0.7
Operating income (loss)	0.4	5.3	(1.8)	6.3
Net income (loss)	(0.5)	0.8	0.2	2.8

Net Sales by Product Category and Reporting Segment

The following tables provide net sales by major product category by reporting segment:

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Percentage Change	
	2019	2018	Reported	Constant Currency
Bone Growth Therapies	\$ 50,109	\$ 48,211	3.9%	3.9%
Spinal Implants	23,226	23,880	-2.7%	-2.0%
Biologics	16,744	14,668	14.2%	14.2%
Global Spine	90,079	86,759	3.8%	4.0%
Global Extremities	25,771	24,788	4.0%	8.5%
Net sales	\$ 115,850	\$ 111,547	3.9%	5.0%

(U.S. Dollars, in thousands)	Six Months Ended June 30,		Percentage Change	
	2019	2018	Reported	Constant Currency
Bone Growth Therapies	\$ 97,392	\$ 94,374	3.2%	3.2%
Spinal Implants	46,129	44,587	3.5%	4.3%
Biologics	32,476	29,003	12.0%	12.0%
Global Spine	175,997	167,964	4.8%	5.0%
Global Extremities	48,965	52,292	-6.4%	-1.4%
Net sales	\$ 224,962	\$ 220,256	2.1%	3.5%

Global Spine

Global Spine offers the following products categories:

- Bone Growth Therapies, which 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.
- Spinal Implants, which designs, develops and markets a broad portfolio of motion preservation and 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.
- Biologics, which provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. Biologics markets its tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives.

Three months ended June 30, 2019 compared to 2018

Net sales increased \$3.3 million or 3.8%

- Bone Growth Therapies net sales increased \$1.9 million or 3.9%, primarily driven by an increase in order volume in the quarter, partially offset by customer sales mix and product mix changes
- Spinal Implants net sales decreased \$0.7 million or 2.7%, primarily driven by abnormally high pricing pressures and ongoing disruption in our legacy sales force in preparation of bringing on larger sales partners in key geographies, which is expected to be reduced as we gain traction with our new distributors, and partially offset by an increase in Motion Preservation sales of \$0.8 million
- Biologics net sales increased \$2.1 million or 14.2%, primarily due to distribution added during the last year and recovery in a previously underperforming region, as volume increased related to Trinity tissues by 17.3%, partially offset by a low single-digit price decline

Six months ended June 30, 2019 compared to 2018

Net sales increased \$8.0 million or 4.8%

- Bone Growth Therapies net sales increased \$3.0 million or 3.2%, primarily driven by an increase in order volume in the quarter, partially offset by customer sales mix and product mix changes
- Spinal Implants net sales increased \$1.5 million or 3.5%, primarily driven by an increase of \$3.9 million in Motion Preservation sales as we acquired Spinal Kinetics during the second quarter of 2018, and partially offset by a decrease in legacy U.S. sales of \$2.4 million, primarily resulting from ongoing disruption in our legacy sales force in preparation of bringing on larger sales partners in key geographies, the impact of which is expected to be reduced as we gain traction with our new distributors and pricing pressures
- Biologics net sales increased \$3.5 million or 12.0%, primarily due to distribution added during the last year and recovery in a previously underperforming region, as volume increased related to Trinity tissues by 18.4%, partially offset by a low single-digit price decline as well as a contractual reduction in the marketing services fee we receive from MTF Biologics, which became effective during the first quarter of 2018

Global Extremities

Global Extremities offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. Global 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 June 30, 2019 compared to 2018

Net sales increased \$1.0 million or 4.0%

- Increase of \$2.2 million largely attributed to variability in the timing of orders from our stocking distributors and growth in our direct-sales markets
- Partially offset by a decrease of \$1.1 million due to the changes in foreign currency exchange rates, which had a negative impact on net sales

Six months ended June 30, 2019 compared to 2018

Net sales decreased \$3.3 million or 6.4%

- Decrease of \$2.6 million due to the changes in foreign currency exchange rates, which had a negative impact on net sales
- Decrease of \$0.7 million largely attributed to variability in the timing of orders from our stocking distributors

Gross Profit

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Net sales	\$ 115,850	\$ 111,547	3.9%	\$ 224,962	\$ 220,256	2.1%
Cost of sales	25,812	22,835	13.0%	49,520	46,982	5.4%
Gross profit	\$ 90,038	\$ 88,712	1.5%	\$ 175,442	\$ 173,274	1.3%
Gross margin	77.7%	79.5%	-1.8%	78.0%	78.7%	-0.7%

Three months ended June 30, 2019 compared to 2018

Gross profit increased \$1.3 million

- Increase primarily due to the growth in net sales and partially offset by a decrease in gross margin, which decreased to 77.7% compared to 79.5% in the prior year period, largely due to higher than normal charges related to the buildup of Spinal Implants inventory to support sales growth from our new sales partners in key geographies

Six months ended June 30, 2019 compared to 2018

Gross profit increased \$2.2 million

- Increase primarily due to the growth in net sales and partially offset by a decrease in gross margin, which decreased to 78.0% compared to 78.7% in the prior year period, largely due to higher than normal charges related to the buildup of Spinal Implants inventory to support sales growth from our new sales partners in key geographies

Sales and Marketing Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Sales and marketing	\$ 56,864	\$ 51,529	10.4%	\$ 110,558	\$ 101,797	8.6%
As a percentage of net sales	49.1%	46.2%	2.9%	49.1%	46.2%	2.9%

Three months ended June 30, 2019 compared to 2018

Sales and marketing expense increased \$5.3 million

- Increase largely attributable to increases in headcount, training and education costs, and increased marketing efforts to support growth and the launch of the M6-C artificial cervical disc in the U.S.
- Further increases relate to higher variable compensation rates to support growth in our Biologics product category

Six months ended June 30, 2019 compared to 2018

Sales and marketing expense increased \$8.8 million

- Increase largely attributable to increases in headcount, training and education costs, and increased marketing efforts to support growth and the launch of the M6-C artificial cervical disc in the U.S.
- Further increases related to higher variable compensation rates to support growth in our Biologics product category

General and Administrative Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
General and administrative	\$ 21,935	\$ 21,958	-0.1%	\$ 42,407	\$ 41,382	2.5%
As a percentage of net sales	18.9%	19.7%	-0.8%	18.9%	18.8%	0.1%

Three months ended June 30, 2019 compared to 2018

General and administrative expense decreased by less than \$0.1 million

- Increase of \$1.3 million attributable to transition and succession charges, including acceleration of certain share-based compensation expense, relating to retirement, transition, or termination of certain named executive officers
- Decrease of \$0.7 million associated with other share-based compensation expenses, excluding the impact of succession charges described above
- Further offset by a decrease of \$0.4 million in certain other compensation expenses

Six months ended June 30, 2019 compared to 2018

General and administrative expense increased \$1.0 million

- Increase of \$4.0 million attributable to transition and succession charges, including acceleration of certain share-based compensation expense, relating to retirement, transition, or termination of certain named executive officers
- Partially offset by a decrease of \$1.7 million in expenses associated with strategic investments, largely due to diligence costs related to the acquisition of Spinal Kinetics and expenses associated with the Domestication in 2018
- Further offset by a decrease of \$1.3 million associated with other share-based compensation expenses, excluding the impact of the succession charges described above

Research and Development Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Research and development	\$ 8,980	\$ 7,891	13.8%	\$ 18,209	\$ 14,828	22.8%
As a percentage of net sales	7.8%	7.0%	0.7%	8.1%	6.7%	1.4%

Three months ended June 30, 2019 compared to 2018

Research and development expense increased \$1.1 million

- Increase largely due to additional headcount, the inclusion of one additional month of Motion Preservation expenses as Spinal Kinetics was acquired on April 30, 2018, and increased spend related to clinical trials within the Bone Growth Therapies product category
- Increase also related to costs to comply with recent medical device reporting regulations in the European Union

Six months ended June 30, 2019 compared to 2018

Research and development expense increased \$3.4 million

- Increase 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, which was obtained in February of 2019

Acquisition-related Amortization and Remeasurement

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Acquisition-related amortization and remeasurement	\$ 1,808	\$ 1,419	27.4%	\$ 8,265	\$ 1,482	457.7%
As a percentage of net sales	1.5%	1.3%	0.3%	3.7%	0.7%	3.0%

Acquisition-related amortization and remeasurement consists of amortization related to intangibles acquired through business combinations or asset acquisitions and the remeasurement of any related contingent consideration arrangement.

Three months ended June 30, 2019 compared to 2018

Acquisition-related amortization and remeasurment increased \$0.4 million

- Increase of \$1.0 million related to the amortization of intangible assets acquired through business combinations or asset acquisitions; of this amount, \$0.8 million is attributable to the Spinal Kinetics acquisition, which occurred during the second quarter of 2018 and includes amortization of acquired in-process research and development costs following achievement of the FDA approval milestone during the first quarter of 2019
- Partially offset by a decrease of \$0.6 million related to changes in fair value recognized associated with the FDA milestone, which was achieved and paid during the first quarter of 2019, and potential future revenue-based milestone payments associated with the Spinal Kinetics acquisition

Six months ended June 30, 2019 compared to 2018

Acquisition-related amortization and remeasurement increased \$6.8 million

- Increase of \$3.2 million related to the remeasurement of potential future revenue-based milestone payments associated with the Spinal Kinetics acquisition
- Increase of \$1.6 million related to the remeasurement of the FDA milestone associated with the Spinal Kinetics acquisition, which was achieved and paid during the first quarter of 2019
- Increase of \$2.0 million related to the amortization of intangible assets acquired through business combinations or asset acquisitions; of this amount, \$1.5 million is attributable to the Spinal Kinetics acquisition, which occurred during the second quarter of 2018 and includes amortization of acquired in-process research and development costs following achievement of the FDA milestone during the first quarter of 2019

Non-operating Income and Expense

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Interest income (expense), net	\$ 457	\$ (251)	-282.1%	\$ 200	\$ (434)	-146.1%
Other expense, net	(236)	(3,643)	-93.5%	(640)	(731)	-12.4%

Three months ended June 30, 2019 compared to 2018

Other income (expense) increased \$3.4 million

- Increase of \$3.5 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement gain of \$0.3 million in the second quarter of 2019 compared to a loss of \$3.3 million in the second quarter of 2018

Six months ended June 30, 2019 compared to 2018

Other income (expense) increased less than \$0.1 million

- Increase of \$1.6 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of \$0.6 million in the first half of 2019 compared to a loss of \$2.2 million in the first half of 2018
- Partially offset by a decrease of \$1.5 million related to net unrealized gains recorded in 2018 associated with the increase in fair value of our equity securities in Bone Biologics, Inc. ("Bone Biologics") following the adoption of ASU 2016-01

Income Taxes

(U.S. Dollars, in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Income tax expense (benefit)	\$ 1,219	\$ 1,096	11.2%	\$ (4,787)	\$ 6,469	-174.0%
Effective tax rate	181.4%	54.2%	127.2%	107.9%	51.3%	56.6%

Three months ended June 30, 2019 compared to 2018

The increase in the effective tax compared to the prior year period rate was primarily a result of the following factors:

- Decrease in pre-tax earnings
- Increases in non-deductible executive compensation due to provisions of the Act
- Increases in financial expenses not deductible for tax purposes

The primary factors affecting our effective tax rate for the second quarter of 2019 are as follows:

- Increases in non-deductible executive compensation due to provisions of the Act
- Certain financial expenses not deductible for tax purposes

Six months ended June 30, 2019 compared to 2018

The increase in the effective tax rate compared to the prior year period was primarily a result of the following factors:

- Decrease in pre-tax earnings
- Increases in non-deductible executive compensation due to provisions of the Act
- Increases in financial expenses not deductible for tax purposes
- Benefits related to effective settlement of the 2015 IRS exam and statute expirations

The primary factors affecting our effective tax rate for the six months ended June 30, 2019 are as follows:

- Increases in non-deductible executive compensation due to provisions of the Act
- Certain financial expenses not deductible for tax purposes
- Benefits related to effective settlement of the 2015 IRS exam and statute expirations

Segment Review

As discussed above, we changed the performance measure used to evaluate segment performance from Non-GAAP net margin to EBITDA during the first quarter of 2019. When compared to the prior year period, EBITDA decreased \$0.4 million for the three months ended June 30, 2019 and decreased \$14.7 million for the six months ended June 30, 2019. These changes are largely driven by the fluctuations discussed above. The \$14.7 million decrease for the six months ended June 30, 2019 compared to the prior year period is largely driven by the changes in sales and marketing expense and acquisition-related amortization and remeasurement. The following table reconciles EBITDA to income (loss) before income taxes:

(U.S. Dollars, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Global Spine	\$ 16,523	\$ 19,030	\$ 27,098	\$ 37,855
Global Extremities	2,750	488	2,577	3,816
Corporate	(12,880)	(12,692)	(22,407)	(19,694)
Total EBITDA	\$ 6,393	\$ 6,826	\$ 7,268	\$ 21,977
Depreciation and amortization	(6,178)	(4,554)	(11,905)	(8,923)
Interest income (expense), net	457	(251)	200	(434)
Income (loss) before income taxes	\$ 672	\$ 2,021	\$ (4,437)	\$ 12,620

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at June 30, 2019, totaled \$52.1 million compared to \$72.2 million at December 31, 2018, with the decrease largely a result of \$15.0 million in cash paid in connection with achievement of the Spinal Kinetics FDA Milestone and \$6.4 million related to the acquisition of certain assets of Options Medical, LLC ("Options Medical") in 2019.

(U.S. Dollars, in thousands)	Six Months Ended June 30,		
	2019	2018	Change
Net cash from operating activities	\$ 8,344	\$ 13,032	\$ (4,688)
Net cash from investing activities	(16,738)	(51,549)	34,811
Net cash from financing activities	(11,581)	3,685	(15,266)
Effect of exchange rate changes on cash	(71)	(639)	568
Net change in cash, cash equivalents and restricted cash	\$ (20,046)	\$ (35,471)	\$ 15,425

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.

(U.S. Dollars, in thousands)	Six Months Ended June 30,		
	2019	2018	Change
Net cash from operating activities	\$ 8,344	\$ 13,032	\$ (4,688)
Capital expenditures	(10,338)	(6,652)	(3,686)
Free cash flow	\$ (1,994)	\$ 6,380	\$ (8,374)

Operating Activities

Cash flows from operating activities decreased \$4.7 million

- Decrease in net income of \$5.8 million
- Net increase of \$9.3 million for non-cash gains and losses, largely related to changes in fair value of contingent consideration, depreciation and amortization, share-based compensation expense, and deferred income taxes
- Net decrease of \$8.2 million relating to changes in working capital accounts, primarily attributable to changes in inventories

Two of our primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 63 days at June 30, 2019 compared to 61 days at June 30, 2018. Inventory turns improved to 1.3 times as of June 30, 2019 compared to 1.2 times as of June 30, 2018.

Investing Activities

Cash flows from investing activities increased \$34.8 million

- Increase of \$43.7 million associated with cash paid in relation to the Spinal Kinetics acquisition in 2018, net of cash acquired
- Increase of \$0.7 million associated with the acquisition of certain intangible assets in a transaction with a former distributor and by our additional investment of \$0.5 million in Bone Biologics during the first quarter of 2018
- Partially offset by \$6.4 million associated with cash paid in relation to the acquisition of certain assets of Options Medical, one of our former distributors, during the first quarter of 2019
- Further offset by \$3.7 million attributable to increased capital expenditures compared to the prior year

Financing Activities

Cash flows from financing activities decreased \$15.3 million

- Decrease of \$13.7 million associated with our payment of the FDA Milestone associated with the Spinal Kinetics acquisition during the first quarter of 2019, which represents the acquisition-date fair value attributable to the FDA Milestone liability originally recognized
- Decrease in net proceeds of \$0.8 million from the issuance of common shares
- Decrease of \$0.2 million attributable to principal payments made during 2019 relating to our finance lease and \$0.6 million attributable to other financing cash flows, which primarily relate to deferred payments made associated with the acquisition of certain intangible assets in transactions with former distributors

Credit Facilities

There have been no material changes to our credit facilities as disclosed in our Form 10-K for the year ended December 31, 2018.

Other

For information regarding Contingencies, see Note 9 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Spinal Kinetics Acquisition

As part of the consideration for the Spinal Kinetics acquisition, we agreed to milestone payments in the future of up to \$60.0 million in cash. One milestone payment was for \$15.0 million upon FDA approval of Spinal Kinetics' M6-C artificial cervical disc (the "FDA Milestone"). During the first quarter of 2019, we obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration and the FDA Milestone payment was triggered. We paid the \$15.0 million FDA Milestone payment on February 14, 2019 from cash on hand.

Two other milestone payments are comprised of revenue-based milestone payments of up to \$45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The fair value of the contingent consideration arrangement as of June 30, 2019 was \$19.4 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. The remaining liability attributable to the revenue-based milestones is included within other long-term liabilities. For additional discussion of this matter, see Note 7 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

eNeura debt security

We hold a debt security of eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The debt security was originally set to mature on March 4, 2019. On March 1, 2019, we entered into an Amended and Restated Senior Secured Promissory Note with eNeura (the "Restructured Debt Security") to restructure the debt security, which extended the maturity date to the earlier of (i) March 4, 2022, (ii) the effective date of a change in control, or (iii) the effective date of an initial public offering by eNeura. As consideration for the extension, eNeura issued to us a Warrant to Purchase Common Stock (the "Warrant"), exercisable at \$0.01 per share over a ten year contractual term, for a number of shares equal to 10% of the sum of the outstanding principal and accrued interest on the Amended and Restated Debt Security as of March 1, 2019, divided by \$1.00 (subject to certain anti-dilution provisions).

We considered the restructuring of the eNeura debt security to be a Troubled Debt Restructuring (“TDR”). A TDR exists when a creditor for economic or legal reasons related to the debtor’s financial difficulties grants a concession to the debtor that it would not otherwise consider. In making this determination, we considered eNeura’s current financial condition and whether the restructuring of the debt security resulted in the granting of a concession after taking into account all the facts and circumstances surrounding the restructuring. The restructuring was undertaken to improve the likelihood of our effort to recover the investment in the original the debt security.

As a result of the restructuring, the eNeura debt security is no longer accounted for at fair value, but rather in accordance with the accounting required for TDRs. The fair value of the debt security immediately prior to the restructuring was reclassified to be the carrying amount of the debt security, as such amount approximates our estimate of future cash collections discounted using the debt security’s effective interest rate of 8%. Our estimate of future cash flows involves significant judgment regarding the timing, expected events, and amount of future cash collections. Decreases in our estimate of future cash collections could result in a significant other-than-temporary impairment. Interest income on the restructured eNeura debt security is recorded using the interest income method; therefore, the amortized cost basis is accreted up to the amount of expected future cash flows over the term of the Restructured Debt Security. For additional information, see Notes 7 and 8 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Brazil

On April 3, 2019, our appeal regarding the freezing of our local bank accounts in Brazil was heard by the Brazil Federal Court of Appeals of Rio de Janeiro, in which the Court ordered the unfreezing of the cash. Approximately \$2.5 million was then returned without any restrictions in April 2019. As such, this balance has been reclassified to cash and cash equivalents as of June 30, 2019. For additional discussion regarding the matter, see Note 9 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Off-balance Sheet Arrangements

As of June 30, 2019, 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, 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, 2018. There have been no significant changes to our critical accounting estimates except for the following:

Leases

On January 1, 2019, we adopted ASU 2016-02, Leases (Topic 842). We determine if an arrangement is a lease at inception. Lease assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As our leases do not provide an implicit rate, our incremental borrowing rate is used as a discount rate, based on the information available at the commencement date, in determining the present value of lease payments. Lease assets also include the impact of any prepayments made and are reduced by impact of any lease incentives. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for these leases on a straight-line basis over the lease term. Lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise the option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

We have made a policy election for all classifications of leases to combine lease and nonlease components and to account for them as a single lease component. Variable lease payments are excluded from the lease liability and recognized in the period in which the obligation is incurred.

Recently Issued Accounting Pronouncements

See Note 2 of the Notes to the Unaudited Condensed Consolidated Financial Statements for detailed information regarding the status of recently issued accounting pronouncements.

Non-GAAP Financial Measures

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater transparency to the information used by senior management in its financial and operational decision-making. We believe it is important to provide investors with the same non-GAAP metrics used to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to historical operating results and internally evaluate the effectiveness of the our operating strategies. Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial measures.

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

Constant Currency

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

EBITDA

EBITDA is a non-GAAP metric defined as earnings before interest income (expense), net, income taxes, depreciation, and amortization. EBITDA is the primary metric used by our Chief Operating Decision Maker in managing the business.

Free Cash Flow

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes to our market risks as disclosed in our Form 10-K for the year ended December 31, 2018.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that the information required to be disclosed in reports filed or submitted under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. These include controls and procedures designed to ensure that this information is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Management, with the participation of the President and Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. 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 June 30, 2019.

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 9 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, 2018.

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

We have not made any repurchases of our common stock during the second quarter of 2019.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

There are no matters to be reported under this heading.

Item 6. Exhibits

- 10.1 [Consulting Agreement, dated July 15, 2019, between Bradley V. Niemann and Orthofix Medical Inc. \(filed as an exhibit to the Company's Current Report on Form 8-K filed on July 15, 2019 and incorporated herein by reference\).](#)
- 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 Inline eXtensible Business Reporting Language("iXBRL"), filed herewith: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Changes in Shareholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.

* 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: August 5, 2019

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

Date: August 5, 2019

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 June 30, 2019, 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: August 5, 2019

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 June 30, 2019, 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: August 5, 2019

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 June 30, 2019, (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: August 5, 2019

/s/ BRADLEY R. MASON

Name: Bradley R. Mason

Title: President and Chief Executive Officer

Dated: August 5, 2019

/s/ DOUG RICE

Name: Doug Rice

Title: Chief Financial Officer