ORTHOFIX INTERNATIONAL N V
Form 10-Q
April 30, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

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

7 Abraham de Veerstraat

| | |
|---|---|
| Curaçao | Not applicable |
| (Address of principal executive offices) | (Zip Code) |

599-9-4658525

(Registrant's telephone number, including area code)

Not applicable

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

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

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

As of April 23, 2018, 18,757,700 shares of common stock were issued and outstanding.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other c terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict , including the risks described Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "2017 Form 10-K") and other SEC filings. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, or the risk factors described in the 2017 Form 10-K and other SEC filings, to reflect new information, the occurrence of future events or circumstances or otherwise.

Trademarks

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Balance Sheets

| (U.S. Dollars, in thousands, except share data) | March 31, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $ 77,056 | $ 81,157 |
| Accounts receivable, net of allowances of $8,934 and $8,405, respectively | 77,182 | 63,437 |
| Inventories | 77,686 | 81,330 |
| Prepaid expenses and other current assets | 31,219 | 25,877 |
| Total current assets | 263,143 | 251,801 |
| Property, plant and equipment, net | 43,973 | 45,139 |
| Patents and other intangible assets, net | 13,150 | 10,461 |
| Goodwill | 53,565 | 53,565 |
| Deferred income taxes | 28,359 | 23,315 |
| Other long-term assets | 6,814 | 21,073 |
| Total assets | $ 409,004 | $ 405,354 |
| Liabilities and shareholders' equity | | |
| Current liabilities | | |
| Accounts payable | $ 14,012 | $ 18,111 |
| Other current liabilities | 51,171 | 61,295 |
| Total current liabilities | 65,183 | 79,406 |
| Other long-term liabilities | 30,647 | 29,340 |
| Total liabilities | 95,830 | 108,746 |
| Contingencies (Note 5) | | |
| Shareholders' equity | | |
| Common shares $0.10 par value; 50,000,000 shares authorized; 18,405,344 and 18,278,833 issued and outstanding as of March 31, 2018 and December 31, 2017, respectively | 1,841 | 1,828 |
| Additional paid-in capital | 228,356 | 220,591 |
| Retained earnings | 78,493 | 70,402 |
| Accumulated other comprehensive income | 4,484 | 3,787 |
| Total shareholders' equity | 313,174 | 296,608 |
| Total liabilities and shareholders' equity | $ 409,004 | $ 405,354 |

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

ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

| | Three Months Ended March 31, | |
|---|---|---|
| (Unaudited, U.S. Dollars, in thousands, except share and per share data) | 2018 | 2017 |
| Net sales | $108,709 | $102,738 |
| Cost of sales | 24,147 | 22,581 |
| Gross profit | 84,562 | 80,157 |
| Sales and marketing | 50,268 | 48,532 |
| General and administrative | 19,484 | 18,282 |
| Research and development | 6,937 | 7,424 |
| Operating income | 7,873 | 5,919 |
| Interest income (expense), net | (183) | 45 |
| Other income (expense), net | 2,912 | (4,348) |
| Income before income taxes | 10,602 | 1,616 |
| Income tax expense | (5,373) | (3,924) |
| Net income (loss) from continuing operations | 5,229 | (2,308) |
| Discontinued operations (Note 5) | | |
| Loss from discontinued operations | (3) | (527) |
| Income tax benefit | — | 181 |
| Net loss from discontinued operations | (3) | (346) |
| Net income (loss) | $5,226 | $(2,654) |
| Net income (loss) per common share—basic | | |
| Net income (loss) from continuing operations | $0.28 | $(0.13) |
| Net loss from discontinued operations | — | (0.02) |
| Net income (loss) per common share—basic | $0.28 | $(0.15) |
| Net income (loss) per common share—diluted | | |
| Net income (loss) from continuing operations | $0.27 | $(0.13) |
| Net loss from discontinued operations | — | (0.02) |
| Net income (loss) per common share—diluted | $0.27 | $(0.15) |
| Weighted average number of common shares: | | |
| Basic | 18,404,856 | 17,979,675 |
| Diluted | 18,874,591 | 17,979,675 |
| | | |
| Other comprehensive income, before tax | | |
| Unrealized gain (loss) on debt securities | — | (3,220) |
| Reclassification adjustment for loss on debt securities in net income | — | 5,585 |
| Currency translation adjustment | 697 | 234 |
| Other comprehensive income before tax | 697 | 2,599 |
| Income tax related to items of other comprehensive loss | — | (900) |
| Other comprehensive income, net of tax | 697 | 1,699 |
| Comprehensive income (loss) | $5,923 | $(955) |

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

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ORTHOFIX INTERNATIONAL N.V.

Condensed Consolidated Statements of Cash Flows

| | Three Months Ended | |
|---|---|---|
| | March 31, | |
| (Unaudited, U.S. Dollars, in thousands) | 2018 | 2017 |
| Cash flows from operating activities | | |
| Net income (loss) | $5,226 | $(2,654) |
| Adjustments to reconcile net income to net cash from operating activities | | |
| Depreciation and amortization | 4,369 | 5,075 |
| Amortization of debt costs and other assets | 375 | 360 |
| Provision for doubtful accounts | (35) | 532 |
| Deferred income taxes | 277 | 5,074 |
| Share-based compensation | 3,916 | 2,816 |
| Other-than-temporary impairment on debt securities | — | 5,585 |
| Gain on valuation of equity securities | (1,629) | — |
| Other | 208 | 242 |
| Changes in operating assets and liabilities | | |
| Accounts receivable | (4,925) | (2,074) |
| Inventories | 1,664 | (2,750) |
| Prepaid expenses and other current assets | 2,166 | (203) |
| Accounts payable | (4,459) | 1,014 |
| Other current liabilities | (11,310) | (23,253) |
| Other long-term assets and liabilities | 597 | (663) |
| Net cash from operating activities | (3,560) | (10,899) |
| Cash flows from investing activities | | |
| Capital expenditures for property, plant and equipment | (2,831) | (3,721) |
| Capital expenditures for intangible assets | (607) | (184) |
| Purchase of intangible assets and other investments | (1,217) | — |
| Other investing activities | — | 474 |
| Net cash from investing activities | (4,655) | (3,431) |
| Cash flows from financing activities | | |
| Proceeds from issuance of common shares | 4,378 | 3,876 |
| Payments related to withholdings for share-based compensation | (516) | (2,079) |
| Payment of debt issuance costs | (165) | — |
| Net cash from financing activities | 3,697 | 1,797 |
| Effect of exchange rate changes on cash | 417 | 244 |
| Net change in cash, cash equivalents, and restricted cash | (4,101) | (12,289) |
| Cash, cash equivalents, and restricted cash at the beginning of the period | 81,157 | 53,941 |
| Cash, cash equivalents, and restricted cash at the end of the period | $77,056 | $41,652 |
| | | |
| Noncash activities: | | |
| Purchase of intangible assets | 1,181 | — |

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

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ORTHOFIX INTERNATIONAL N.V.

Notes to the Unaudited Condensed Consolidated Financial Statements

Business and basis of presentation

Orthofix International N.V., together with its subsidiaries (the "Company") is a global medical device company focused on musculoskeletal healing products and value-added services. Headquartered in Lewisville, Texas, the Company has four strategic business units ("SBUs") that are also its reporting segments: BioStim, Extremity Fixation, Spine Fixation, and Biologics.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair statement have been included. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes contained in the Company's Form 10-K for the year ended December 31, 2017. Operating results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2018.

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

1. Recently adopted accounting standards and recently issued accounting pronouncements

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

In May 2014, the FASB issued ASU 2014-09. Topic 606 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective transition method. Results for prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under the previous revenue recognition standard, Topic 605. See Note 7 for further details.

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

In January 2016, the FASB issued ASU 2016-01, which was then further clarified in ASU 2018-03, in February 2018. This guidance requires entities to generally measure equity investments at fair value and recognize any changes in fair value in net income. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows entities to choose to measure these investments using a new measurement alternative, which values the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. The Company prospectively adopted both ASU 2016-01 and ASU 2018-03 on January 1, 2018 and elected to use the new measurement alternative for the Company's equity investments in Bone Biologics, Inc. ("Bone Biologics"), which have historically been held at cost. This resulted in an increase in the previously recorded value of the Company's equity investments in Bone Biologics, which are recorded within other long term assets, of $1.6 million, or $0.09 per share before taxes, which was included in other income. See Note 4 for further details.

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

In October 2016, the FASB issued ASU 2016-16, which reduces diversity in practice of accounting for intra-entity transfers of assets, particularly for intra-entity transfers of intellectual property. The new standard states an entity should recognize the income tax consequences of an intra-entity transfer when the transfer occurs, as opposed to historical U.S. GAAP guidance which prohibited the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset had been sold to an outside party. During the third and fourth quarters of 2017, the Company executed two intra-entity asset transfers that resulted in prepaid income taxes of $8.6 million. The Company adopted this new standard using a modified retrospective approach as of January 1, 2018, which

resulted in a reduction of prepaid income taxes and an increase in deferred tax assets with these changes offset by an adjustment to the Company's opening retained earnings of approximately $1.9 million. Adoption of this guidance did not have a material impact to the Company’s consolidated statements of operations and comprehensive income (loss) or to its consolidated statements of cash flows.

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

In November 2016, the FASB issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. The Company adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in a decrease in net cash from operating activities of $14.4 million for the three months ended March 31, 2017.

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

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

Recently issued accounting pronouncements

| Topic | Description of Guidance | Effective Date | Status of Company's Evaluation |
|---|---|---|---|
| Leases (ASU 2016-02) | Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach. | January 1, 2019 | The Company has established a cross-functional implementation team to analyze the impact of the standard on the Company's population of leases and to evaluate the Company's current accounting policies relating to leases. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will materially impact the Company's consolidated balance sheet, resulting in current operating lease obligations being reflected on the consolidated balance sheet. |
| Goodwill (ASU 2017-04) | Eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment loss will instead be measured at the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the recorded amount of | 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. |

| | | | |
|---|---|---|---|
| | goodwill. Applied on a prospective basis, with early adoption permitted. | | |
| Comprehensive income<br><br>(ASU 2018-02) | Allows entities to reclassify from accumulated other comprehensive income to retained earnings stranded tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act"). Applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Act is recognized. | January 1, 2019 | The Company is currently evaluating the impact this ASU may have on its consolidated financial statements. |

2. Inventories

Inventories were as follows:

| (U.S. Dollars, in thousands) | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 5,889 | $ 6,067 |
| Work-in-process | 13,666 | 12,487 |
| Finished products | 58,131 | 60,441 |
| Deferred cost of sales | — | 2,335 |
| Inventories | $ 77,686 | $ 81,330 |

Prior to the adoption of ASU 2014-09, or for all periods presented prior to January 1, 2018, deferred cost of sales resulted from transactions where the Company had shipped product or performed services for which all revenue recognition criteria had not yet been met. Once all revenue recognition criteria had been met, the revenue and associated cost of sales were recognized. Subsequent to the adoption of ASU 2014-09, the Company no longer has transactions which result in the recognition of deferred cost of sales. See Note 7 for further discussion of the Company’s adoption of ASU 2014-09.

3. Long-term debt

As of March 31, 2018, the Company has not made any borrowings under the five year $125 million secured revolving credit facility it entered into in August 2015 with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lenders. The Company has also not made any borrowings on its €5.8 million ($7.1 million) available line of credit in Italy as of March 31, 2018. The Company is in compliance with all required financial covenants as of March 31, 2018.

4. Fair value measurements

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|

| (U.S. Dollars, in thousands) | Level 1 | Level 2 | Level 3 | Total | Total |
|---|---|---|---|---|---|
| Assets | | | | | |
| Collective trust funds | $— | $100 | $— | $100 | $ 100 |
| Treasury securities | 563 | — | — | 563 | 556 |
| Equity warrants | — | 519 | — | 519 | 311 |
| Equity securities | — | 4,379 | — | 4,379 | 2,457 |
| Debt security | — | — | 16,050 | 16,050 | 16,050 |
| Total | $563 | $4,998 | $16,050 | $21,611 | $ 19,474 |
| Liabilities | | | | | |
| Deferred compensation plan | $— | $(1,398) | $— | $(1,398 ) | $ (1,379 ) |
| Total | $— | $(1,398) | $— | $(1,398 ) | $ (1,379 ) |

Equity Warrants and Securities

The Company holds investments in common stock and warrants to purchase shares of common stock of Bone Biologics, Inc. (“Bone Biologics”). Both of these instruments are recorded within other long-term assets. Prior to 2018, these instruments were accounted for at cost as the fair value of these instruments was not readily determinable. Effective January 1, 2018, the Company is required to measure these equity investments at fair value and recognize any changes in fair value in net income as a result of adopting ASU 2016-01. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows entities to choose to measure these investments using a new measurement alternative, which values the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. The Company has elected to use the new measurement alternative for these equity investments in Bone Biologics, which resulted in an increase in the previously recorded value of the equity investments of $1.6 million, or $0.09 per

share before taxes, which was included in other income. In addition, the Company made an additional investment in Bone Biologics during the first quarter of 2018, in which it purchased an additional 250,000 shares of common stock for $0.5 million.

Debt Security

The Company holds a debt security of eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The debt security matures on March 4, 2019. The fair value of the debt security, which is recorded within other current assets, is based upon significant unobservable inputs, including the use of a discounted cash flow model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. As of March 31, 2018, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of $16.1 million, which is consistent with the Company's estimated fair value of the debt security as of December 31, 2017. This compares to an amortized cost basis in the debt security of $9.0 million.

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

| (U.S. Dollars, in thousands) | 2018 | 2017 |
|---|---|---|
| Balance at January 1 | $16,050 | $12,220 |
| Accrued interest income | — | — |
| Gains or losses recorded for the period | | |
| Recognized in net income | — | (5,585 ) |
| Recognized in other comprehensive income | — | 2,365 |
| Balance at March 31 | $16,050 | $9,000 |

5. Contingencies

In addition to the matters described below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. The Company believes any losses related to these matters are individually and collectively immaterial as to a possible loss and range of loss.

Discontinued Operations – Matters Related to Breg and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street"). Under the terms of the agreement, the Company indemnified Water Street and Breg with respect to certain specified matters.

At the time of its divestiture by the Company, Breg was engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases were filed, mostly in California state court. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. Currently pending is a post-close cold therapy claim in California state court.

As of March 31, 2018, the Company has an accrual of $1.7 million recorded within other current liabilities; however, the actual liability could be higher or lower than the amount accrued.

Charges incurred as a result of this indemnification are reflected as discontinued operations in the condensed consolidated statements of operations and comprehensive income (loss).

Italian Medical Device Payback (“IMDP”)

In 2015, the Italian Parliament introduced rules for entities that supply goods and services to the Italian National Healthcare System. The healthcare law is expected to impact the business and financial reporting of companies operating in the medical technology sector that sell medical devices in Italy. A key provision of the law is a ‘payback’ measure, requiring companies selling medical devices in Italy to make payments to the Italian government if medical device expenditures exceed regional maximum ceilings. Companies are required to make payments equal to a percentage of expenditures exceeding maximum regional caps. There is considerable uncertainty about how the law will operate and what the exact timeline is for finalization. The Company’s current assessment of the IMDP involves significant judgment regarding the expected scope and actual implementation terms of the measure as the latter have not been clarified to date by Italian authorities. The Company accounts for the estimated cost of the IMDP as sales and marketing expense and as of March 31, 2018, the Company has accrued €2.6 million ($3.2 million) relating to the IMDP; however, the actual liability could be higher or lower than the amount accrued once the law has been clarified by the Italian authorities.

6. Accumulated other comprehensive loss

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

| (U.S. Dollars, in thousands) | Currency Translation Adjustments | Debt Security | Accumulated Other Comprehensive Loss |
|---|---|---|---|
| Balance at December 31, 2017 | $ (563) | $ 4,350 | $ 3,787 |
| Other comprehensive income | 697 | — | 697 |
| Income taxes | — | — | — |
| Balance at March 31, 2018 | $ 134 | $ 4,350 | $ 4,484 |

7. Revenue recognition and accounts receivable

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

Effective January 1, 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606) using the modified retrospective transition method, which was applied to all contracts. Results for the quarter ended March 31, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under the previous revenue recognition standard, Topic 605.

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

| (U.S. Dollars, in thousands) | December 31, 2017 | Impact of Adoption of ASC 606 | January 1, 2018 |
|---|---|---|---|
| Assets | | | |
| Current assets | | | |
| Cash and cash equivalents | $ 81,157 | $ — | $ 81,157 |
| Accounts receivable, net | 63,437 | 8,648 | 72,085 |
| Inventories | 81,330 | (2,338) | 78,992 |
| Prepaid expenses and other current assets | 25,877 | — | 25,877 |
| Total current assets | 251,801 | 6,310 | 258,111 |
| Deferred income taxes | 23,315 | (1,549) | 21,766 |
| Other long-term assets | 130,238 | — | 130,238 |
| Total assets | $ 405,354 | $ 4,761 | $ 410,115 |

| | | | |
|---|---|---|---|
| Liabilities and shareholders' equity | | | |
| Total liabilities | 108,746 | — | 108,746 |
| Shareholders' equity | | | |
| Common shares | 1,828 | — | 1,828 |
| Additional paid-in capital | 220,591 | — | 220,591 |
| Retained earnings | 70,402 | 4,761 | 75,163 |
| Accumulated other comprehensive income | 3,787 | — | 3,787 |
| Total shareholders' equity | 296,608 | 4,761 | 301,369 |
| Total liabilities and shareholders' equity | $405,354 | $ 4,761 | $410,115 |

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

The table below presents the impact to the Company's consolidated statement of operations for the three months ended March 31, 2018 as a result of the adoption of Topic 606.

| | Three Months Ended March 31, 2018 | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | Based on historical accounting under Topic 605 | Impact of adoption | As reported under Topic 606 |
| Net sales | $101,362 | $7,347 | $108,709 |
| Cost of sales | 22,116 | 2,031 | 24,147 |
| Gross profit | 79,246 | 5,316 | 84,562 |
| Sales and marketing | 50,361 | (93) | 50,268 |
| Other operating expenses | 26,421 | — | 26,421 |
| Operating income | $2,464 | $5,409 | $7,873 |
| Income tax expense | (3,918) | (1,455) | (5,373) |
| Net income from continuing operations | $1,275 | $3,954 | $5,229 |
| Net income from continuing operations per common share—basic | $0.07 | $0.21 | $0.28 |
| Net income from continuing operations per common share—diluted | $0.07 | $0.20 | $0.27 |

Revenue Recognition Under Topic 606

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

BioStim

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

The largest portion of BioStim revenue is derived from third-party payors. This includes commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of the Company's stimulation products. The customer obtains control and revenue is recognized when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or

preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment. Adoption of Topic 606 had an immaterial impact to the BioStim SBU.

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

Extremity Fixation and Spine Fixation

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

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

Certain revenue within the Extremity Fixation and Spine Fixation SBUs are derived from stocking distributors, who purchase the Company's products and then re-sell them directly to customers, such as hospitals. For revenue from stocking distributor arrangements, subsequent to the adoption of Topic 606 effective January 1, 2018, the Company recognizes revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price with stocking distributors is estimated based upon the Company's historical collection experience with the stocking distributor. To derive this estimate, the Company analyzes twelve months of historical invoices by stocking distributor and the subsequent collections on those invoices, for a period of up to 24 months subsequent to the invoice date. This percentage, which is specific to each stocking distributor, is then used to calculate the transaction price. Cost of sales is also recorded upon transfer of control of the product to the customer.

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

Biologics

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

Product Sales and Marketing Service Fees

The table below presents net sales, which includes product sales and marketing service fees, for the three months ended March 31, 2018 and 2017.

| | Three Months Ended March 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 |
| Product sales | $94,889 | $88,401 |
| Marketing service fees | 13,820 | 14,337 |
| Net sales | $108,709 | $102,738 |

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

Trade Accounts Receivable and Allowances

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

Other Contract Assets

The Company's contract assets, excluding trade accounts receivable ("other contract assets"), largely consist of payments made to certain distributors to obtain contracts, gain access to customers in certain territories, and to provide the benefit of the exclusive distribution of Orthofix products. Other contract assets are included in other long-term assets and were $0.8 million and $1.0 million as of March 31, 2018, and December 31, 2017, respectively.

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

8. Business segment information

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

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Change |
| BioStim | $46,163 | $44,539 | 3.6 % |
| Extremity Fixation | 27,504 | 23,945 | 14.9 % |
| Spine Fixation | 20,707 | 19,267 | 7.5 % |
| Biologics | 14,335 | 14,987 | -4.4 % |
| Net sales | $108,709 | $102,738 | 5.8 % |

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

| | Three Months Ended March 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 |
| BioStim | $18,946 | $17,133 |
| Extremity Fixation | 8,158 | 6,412 |
| Spine Fixation | 1,261 | 2,007 |
| Biologics | 6,080 | 6,171 |
| Corporate | (151) | (98) |
| Non-GAAP net margin | $34,294 | $31,625 |

| | | |
|---|---|---|
| General and administrative | 19,484 | 18,282 |
| Research and development | 6,937 | 7,424 |
| Operating income | $7,873 | $5,919 |
| Interest income (expense), net | (183) | 45 |
| Other income (expense), net | 2,912 | (4,348) |
| Income before income taxes | $10,602 | $1,616 |

Geographical information

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

| | Three Months Ended | |
|---|---|---|
| | March 31, | |
| (U.S. Dollars, in thousands) | 2018 | 2017 |
| BioStim | | |
| U.S. | $46,137 | $44,539 |
| International | 26 | — |
| Total BioStim | 46,163 | 44,539 |
| | | |
| Extremity Fixation | | |
| U.S. | 6,916 | 6,579 |
| International | 20,588 | 17,366 |
| Total Extremity Fixation | 27,504 | 23,945 |
| | | |
| Spine Fixation | | |
| U.S. | 17,579 | 16,035 |
| International | 3,128 | 3,232 |
| Total Spine Fixation | 20,707 | 19,267 |
| | | |
| Biologics | | |
| U.S. | 14,322 | 14,963 |
| International | 13 | 24 |
| Total Biologics | 14,335 | 14,987 |
| | | |
| Consolidated | | |
| U.S. | 84,954 | 82,116 |
| International | 23,755 | 20,622 |
| Net sales | $108,709 | $102,738 |

9. Share-based compensation

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

| | Three Months Ended | |
|---|---|---|
| | March 31, | |
| (U.S. Dollars, in thousands) | 2018 | 2017 |
| Cost of sales | $125 | $149 |
| Sales and marketing | 449 | 360 |
| General and administrative | 3,045 | 2,102 |
| Research and development | 297 | 205 |
| | $3,916 | $2,816 |

| (U.S. Dollars, in thousands) | Three Months Ended March 31, 2018 | 2017 |
|---|---|---|
| Stock options | $622 | $595 |
| Time-based restricted stock awards | 1,447 | 1,292 |
| Performance-based restricted stock awards | 489 | 112 |
| Performance-based and market-based restricted stock units | 953 | 466 |
| Stock purchase plan | 405 | 351 |
| | $3,916 | $2,816 |

During the three months ended March 31, 2018 and 2017, the Company issued 126,511 and 214,679 shares, respectively, of common stock related to stock purchase plan issuances, stock option exercises and the vesting of restricted stock awards.

10. 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 March 31, 2018 and 2017, the effective tax rate on continuing operations was 50.7% and 242.8%, respectively. The primary factors affecting the Company's effective tax rate for the three months ended March 31, 2018, were the decrease in the U.S. statutory tax rate enacted in December 2017, the increase in pre-tax earnings, the mix of earnings among tax jurisdictions, and current period losses in certain jurisdictions for which the Company does not currently receive a tax benefit.

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

In the fourth quarter of 2017, the Company recorded tax expense of $8.3 million that represents what it believes is the impact of the enactment of the Tax Act. The expense was based on currently available information and interpretations, which are continuing to evolve, and as a result the expense is considered provisional. The Company has continued to analyze additional information and guidance related to the Tax Act as supplemental legislation, regulatory guidance, or evolving technical interpretations become available. Based on supplemental legislation issued during 2018, the Company recorded tax benefit of $0.5 million in the first quarter of 2018. The Company will continue to refine such amounts within the measurement period as provided by Staff Accounting Bulletin No. 118 and expects to complete its analysis no later than the fourth quarter of 2018.

11. Earnings per share (“EPS”)

For the three months ended March 31, 2018 and 2017, no significant adjustments were made to net income (loss) for purposes of calculating basic and diluted EPS. The following is a reconciliation of the weighted average shares used in diluted EPS computations.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Weighted average common shares-basic | 18,404,856 | 17,979,675 |
| Effect of dilutive securities | | |
| Unexercised stock options and stock purchase plan | 308,537 | — |
| Unvested restricted stock awards and units | 161,198 | — |
| Weighted average common shares-diluted | 18,874,591 | 17,979,675 |

There were 122,678 and 1,019,185 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the three months ended March 31, 2018 and 2017, respectively, because inclusion of these awards was anti-dilutive or, for performance-based and market-based awards, all necessary conditions had not been satisfied by the end of the respective period.

12. Subsequent events

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. Terms of the transaction included $45 million in cash plus up to an additional $60 million in future contingent milestone payments related to U.S. Food and Drug Administration approval of the M6-C® cervical disc and the achievement of certain future sales targets. These contingent milestones payments must be achieved within five years of closing.

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

The following discussion and analysis of Orthofix International N.V.'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 healing products and value-added services. Headquartered in Lewisville, Texas, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Extremity Fixation, Spine Fixation, and Biologics. Our products are widely distributed by our sales representatives and distributors.

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

- Net sales were $108.7 million, an increase of 5.8% on a reported basis and 3.3% on a constant currency basis
- Increase in non-GAAP net margin of $2.7 million, or 8.4%, and an increase as a percentage of sales from 30.8% in the first quarter of 2017 to 31.5% in the first quarter of 2018
- Received U.S. Food and Drug Administration and European CE Mark approvals for our next-generation PhysioStim bone growth stimulators accompanied by our STIM onTrack mobile application
- Entered into a definitive merger agreement with Spinal Kinetics, a privately held developer and manufacturer of artificial cervical and lumbar discs, and completed the acquisition on April 30, 2018

Results of Operations

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (%) | (%) |
| Net sales | 100.0 | 100.0 |
| Cost of sales | 22.2 | 22.0 |
| Gross profit | 77.8 | 78.0 |
| Sales and marketing | 46.3 | 47.2 |
| General and administrative | 17.9 | 17.8 |
| Research and development | 6.4 | 7.2 |
| Operating income | 7.2 | 5.8 |
| Net income (loss) from continuing operations | 4.8 | (2.2) |

Net Sales by Strategic Business Unit

The following tables provide net sales by SBU:

| | Three Months Ended March 31, | | Percentage Change | |
|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Reported | Constant Currency |
| BioStim | $46,163 | $44,539 | 3.6 % | 3.6 % |
| Extremity Fixation | 27,504 | 23,945 | 14.9 % | 4.3 % |
| Spine Fixation | 20,707 | 19,267 | 7.5 % | 7.2 % |
| Biologics | 14,335 | 14,987 | -4.4 % | -4.4 % |
| Net sales | $108,709 | $102,738 | 5.8 % | 3.3 % |

BioStim

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

Three months ended March 31, 2018 compared to 2017

Net sales increased $1.6 million, or 3.6%

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

Extremity Fixation

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

Three months ended March 31, 2018 compared to 2017

Net sales increased $3.6 million or 14.9%

- Increase largely due to the change in foreign currency exchange rates, which had a positive impact on 2018 net sales of $2.5 million
- Increase in sales resulting from continued uptake of new products and good performance in all but a few of our global markets, including continued momentum in the U.S.

Spine Fixation

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

Three months ended March 31, 2018 compared to 2017

Net sales increased $1.4 million or 7.5%

- Increase in U.S. sales due to the addition of new distributor partners in late 2016 and in 2017 and the uptake of recent product introductions, including our Polyetheretherketone (“PEEK”) / Titanium Composite (“PTC”) family product lines, Cetra, and Forza XP systems
- Partially offset by a net decrease in year-over-year international sales

Biologics

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

Three months ended March 31, 2018 compared to 2017

Net sales decreased $0.7 million or 4.4%

- Decrease largely due to a modest increase in pricing pressure for our Trinity ELITE and Trinity Evolution tissues ("Trinity tissues") and a contractual decrease in the fee we receive for marketing service fees for our Trinity tissues from MTF Biologics
- Partially offset by a slight increase in volume for our Trinity tissues

Gross Profit and Non-GAAP Net Margin

| | Three Months Ended March 31, | | | | | |
|---|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | | 2017 | | % Change | |
| Gross profit | $84,562 | | $80,157 | | 5.5 | % |
| Sales and marketing | (50,268) | | (48,532) | | 3.6 | % |
| Non-GAAP net margin | $34,294 | | $31,625 | | 8.4 | % |
| | | | | | | |
| Gross margin | 77.8 | % | 78.0 | % | -0.2 | % |
| Non-GAAP net margin as a percentage of net sales | 31.5 | % | 30.8 | % | 0.7 | % |

Three months ended March 31, 2018 compared to 2017

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

- Gross profit increased $4.4 million, primarily due to the growth in net sales, partially offset by an unfavorable impact from our sales mix this quarter
- Sales and marketing expense increased $1.7 million, primarily due to higher commission and compensation-related expenses in the first quarter of 2018 due to the increase in net sales; however, sales and marketing expenses decreased as a percentage of sales, largely due to lower commission rates as well as decreased spending in marketing-related expenses
- Non-GAAP net margin increased by $2.7 million as a result of the changes in gross profit and sales and marketing expense

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

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | % Change | |
| BioStim | $18,946 | $17,133 | 10.6 | % |
| Extremity Fixation | 8,158 | 6,412 | 27.2 | % |
| Spine Fixation | 1,261 | 2,007 | -37.2 | % |
| Biologics | 6,080 | 6,171 | -1.5 | % |
| Corporate | (151) | (98) | 54.1 | % |
| Non-GAAP net margin | $34,294 | $31,625 | 8.4 | % |

General and Administrative Expense

| | Three Months Ended March 31, | | | | % | |
|---|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | | 2017 | | Change | |
| General and administrative | $19,484 | | $18,282 | | 6.6 | % |
| As a percentage of net sales | 17.9 | % | 17.8 | % | 0.1 | % |

Three months ended March 31, 2018 compared to 2017

General and administrative expense increased $1.2 million

- Increase of $1.7 million in expenses associated with strategic investments, such as our due diligence efforts in connection with the Spinal Kinetics merger and our preparation to move the domicile of the Company
- Increase in share-based compensation expense of $0.9 million, largely related to increases in expense attributable to our performance-based and market-based awards
- Partially offset by decreases in core general and administrative costs relating to other professional fees of $0.9 million and compensation and benefits of $0.6 million, of which a portion is a result of our recent restructuring and optimization initiatives

Research and Development Expense

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | % Change |
| Research and development | $6,937 | $7,424 | -6.6 % |
| As a percentage of net sales | 6.4 % | 7.2 % | -0.8 % |

Three months ended March 31, 2018 compared to 2017

Research and development expense decreased $0.5 million

- Decrease in costs associated with clinical trials of $0.3 million due the timing and status of each of our ongoing projects
- Decrease associated with cost savings from our 2017 U.S. restructuring initiative

Non-operating Income and Expense

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | % Change |
| Interest income (expense), net | $(183) | $45 | -506.7 % |
| Other income (expense), net | 2,912 | (4,348) | -167.0 % |

Three months ended March 31, 2018 compared to 2017

Other income (expense) increased $7.3 million

- In the first quarter of 2017, we recorded an other-than-temporary impairment on the eNeura debt security of $5.6 million before income taxes
- In the first quarter of 2018, we recorded an unrealized gain of $1.6 million associated with the increase in fair value of our equity securities in Bone Biologics following the adoption of ASU 2016-01

Income Taxes

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | % Change |
| Income tax expense | $5,373 | $3,924 | 36.9 % |
| Effective tax rate | 50.7 % | 242.8% | -192.1 % |

Three months ended March 31, 2018 compared to 2017

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

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

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

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

Liquidity and Capital Resources

Cash and cash equivalents at March 31, 2018, were $77.1 million compared to $81.2 million at December 31, 2017.

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Change |
| Net cash from operating activities | $(3,560) | $(10,899) | $7,339 |
| Net cash from investing activities | (4,655) | (3,431) | (1,224) |
| Net cash from financing activities | 3,697 | 1,797 | 1,900 |
| Effect of exchange rate changes on cash | 417 | 244 | 173 |
| Net change in cash and cash equivalents | $(4,101) | $(12,289) | $8,188 |

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.

| | Three Months Ended March 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Change |
| Net cash from operating activities | $(3,560) | $(10,899) | $7,339 |
| Capital expenditures | (3,438) | (3,905) | 467 |
| Free cash flow | $(6,998) | $(14,804) | $7,806 |

Operating Activities

Cash flows from operating activities increased $7.3 million

- Increase in net income of $7.9 million
- Net decrease of $12.2 million for non-cash gains and losses, largely related to the other-than-temporary impairment on the eNeura debt security in the first quarter of 2017, deferred income taxes, and the increased valuation of our equity securities related to Bone Biologics, and partially offset by changes in share-based compensation expense
- Net increase of $11.7 million relating to changes in working capital accounts, primarily attributable to changes in other current liabilities, accounts payable, and inventories

Our two primary working capital accounts are accounts receivable and inventory. Days sales in receivables were 64 days at March 31, 2018 compared to 52 days at March 31, 2017, with the increase largely attributable to our adoption of Accounting Standards Update (“ASU”) 2014-09. Inventory turns were 1.2 times as of March 31, 2018 compared to 1.3 times at March 31, 2017.

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

In November 2016, the FASB issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. The Company adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in a decrease in net cash from operating activities of $14.4 million for the three months ended March 31, 2017.

Investing Activities

Cash flows from investing activities decreased $1.2 million

- Decrease of $0.7 million associated with the acquisition of certain intangible assets in a transaction with a former distributor during the first quarter of 2018
- Decrease of $0.5 million due to our additional investment in Bone Biologics, Inc. during 2018
- Decrease of $0.5 million due to proceeds received in 2017 upon the maturity of certain time-based deposits
- Partially offset by a reduction in capital expenditures of $0.5 million

Financing Activities

Cash flows from financing activities increased $1.9 million

- Increase in net proceeds of $2.1 million from the issuance of common shares

Credit Facilities

There have been no material changes to our debt instruments as disclosed in our Form 10-K for the year ended December 31, 2017.

Other

For information regarding Contingencies, see Note 5 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein.

Spinal Kinetics Merger Agreement

On March 15, 2018, we entered into a definitive merger agreement with Spinal Kinetics, a privately held developer and manufacturer of artificial cervical and lumbar discs. As consideration, we agreed to pay an aggregate of $45 million in cash, subject to certain adjustments, upon closing plus milestone payments in the future of up to $60 million in cash. We closed on the acquisition on April 30, 2018 and paid the $45 million of cash due at close with cash on hand. For additional discussion of this matter see Note 12 of the Notes to the Unaudited Condensed Consolidated Financial Statements.

Off-balance Sheet Arrangements

As of March 31, 2018, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors, except for the Merger Agreement with Spinal Kinetics discussed above.

Contractual Obligations

There have been no material changes in any of our material contractual obligations as disclosed in our Form 10-K for the year ended December 31, 2017.

Critical Accounting Estimates

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

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

Revenue Recognition

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

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

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products, we recognize revenue when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or

allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

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

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

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

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

Subsequent to the adoption of Topic 606, effective January 1, 2018, for revenue derived from stocking distributor arrangements, we recognize revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price is estimated based upon our historical collection experience with the stocking distributor. To derive this estimate, we analyze twelve months of historical invoices by stocking distributor and the subsequent collections on those invoices, for a period of up to 24 months subsequent to the invoice date. This percentage, which is specific to each stocking distributor, is then used to calculate the transaction price. Cost of sales is also recorded upon transfer of control of the product to the customer, which is when the Company’s performance obligation has been satisfied.

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

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collections, write-offs, and payor reimbursement experience are integral parts of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to

net sales. Our estimates are periodically tested against actual collection experience. Our allowance for doubtful accounts and estimation of contractual allowances are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, net margin, operating income, net income, and trade accounts receivable.

Recently Issued Accounting Pronouncements

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

Non-GAAP Financial Measures

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater transparency to the information used by senior management in its financial and operational decision-making. We believe it is important to provide

investors with the same non-GAAP metrics used to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to historical operating results and internally evaluate the effectiveness of the our operating strategies. Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial measures.

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

Constant Currency

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

Non-GAAP Net Margin

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

Free Cash Flow

Free cash flow is calculated by subtracting capital expenditures from net cash from operating activities. Free cash flow is an important indicator of how much cash is generated or used by our normal business operations, including capital expenditures. Management uses free cash flow as a measure of progress on its capital efficiency and cash flow initiatives. In the first quarter of 2018, we adopted ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. We adopted this accounting standard using a retrospective transition approach, which resulted in a decrease in net cash from operating activities of $14.4 million for the three months ended March 31, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes to our market risks as disclosed in our Form 10-K for the year ended December 31, 2017.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that the information required to be disclosed in reports filed or submitted under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules

and forms. These include controls and procedures designed to ensure that this information is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Management, with the participation of the President and Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 31, 2018.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, see Note 5 to the Notes to the Unaudited Condensed Consolidated Financial Statements contained herein, which is incorporated by reference into this Part II, Item 1.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in the “Risk Factors” section of our Form 10-K for the year ended December 31, 2017.

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

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

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

There are no matters to be reported under this heading.

Item 6. Exhibits

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| 2.1* | Agreement and Plan of Merger, entered into March 15, 2018, by and among Blackstone Medical, Inc., Summit Development, Inc., and Spinal Kinetics, Inc. |
| 31.1* | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer. |
| 31.2* | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer. |
| 32.1* | Section 1350 Certifications of each of the Chief Executive Officer and Chief Financial Officer. |
| 101* | The following materials from this Form 10-Q, formatted in Extensible Business Reporting Language ("XBRL"): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Cash Flows and (iv) related notes, detail tagged. |

*Filed herewith.

SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Date: April 30, 2018 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Date: April 30, 2018 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer