

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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

98-1340767
(I.R.S. Employer
Identification No.)

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3451 Plano Parkway,

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

(214) 937-2000

(Registrant's telephone number, including area code)

Orthofix International N.V.

7 Abraham de Veerstraat

Curaçao

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

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

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

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

Large Accelerated filer

Accelerated filer

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

Emerging Growth Company

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

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

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

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Explanatory Note

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

Forward-Looking Statements

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

Trademarks

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ORTHOFIX MEDICAL INC.

Condensed Consolidated Balance Sheets

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

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

ORTHOFIX MEDICAL INC.

Condensed Consolidated Statements of Income and Comprehensive Income

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

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Comprehensive income	\$ 1,278	\$ 6,501	\$ 7,201	\$ 5,546
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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)	2018	2017
Cash flows from operating activities		
Net income	\$6,151	\$1,199
Adjustments to reconcile net income to net cash from operating activities		
Depreciation and amortization	8,923	10,447
Amortization of debt costs and other assets	592	719
Provision for doubtful accounts	(360)	820
Deferred income taxes	724	4,284
Share-based compensation	9,131	5,492
Other-than-temporary impairment on debt securities	—	5,585
Gain on valuation of equity securities	(1,399)	—
Revaluation of contingent consideration	1,109	—
Other	847	572
Changes in operating assets and liabilities, net of effects of acquisition		
Accounts receivable	(363)	(3,787)
Inventories	5,251	(11,119)
Prepaid expenses and other current assets	71	2,199
Accounts payable	(3,847)	(950)
Other current liabilities	(14,612)	(19,407)
Other long-term assets and liabilities	814	(696)
Net cash from operating activities	13,032	(4,642)
Cash flows from investing activities		
Acquisition of business, net of cash acquired	(43,749)	—
Capital expenditures for property, plant and equipment	(5,782)	(7,035)
Capital expenditures for intangible assets	(870)	(1,558)
Asset acquisition and other investments	(1,148)	—
Other investing activities	—	474
Net cash from investing activities	(51,549)	(8,119)
Cash flows from financing activities		
Proceeds from issuance of common shares	5,416	5,282
Payments related to withholdings for share-based compensation	(1,375)	(2,851)
Payment of debt issuance costs and other financing activities	(356)	—
Net cash from financing activities	3,685	2,431
Effect of exchange rate changes on cash	(639)	719
Net change in cash, cash equivalents, and restricted cash	(35,471)	(9,611)
Cash, cash equivalents, and restricted cash at the beginning of the period	81,157	53,941
Cash, cash equivalents, and restricted cash at the end of the period	\$45,686	\$44,330
Supplemental Disclosure of Cash Flow Information:		
Noncash investing activities:		

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

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

ORTHOFIX MEDICAL INC.

Notes to the Unaudited Condensed Consolidated Financial Statements

Business and basis of presentation

Orthofix Medical Inc. (previously Orthofix International N.V.), together with its subsidiaries (the “Company” or “Orthofix”) is a global medical device company focused on musculoskeletal products and therapies. Headquartered in Lewisville, Texas, the Company has four strategic business units (“SBUs”) that are also its reporting segments: BioStim, Spine Fixation, Biologics, and Extremity Fixation.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Pursuant to these rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair statement have been included. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes contained in the Company’s Form 10-K for the year ended December 31, 2017. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for other interim periods or the year ending December 31, 2018.

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

1. Recently adopted accounting standards and recently issued accounting pronouncements

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

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

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

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

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

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

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

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

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

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

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

Recently issued accounting pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Leases (ASU 2016-02)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach.	January 1, 2019	The Company has established a cross-functional implementation team to analyze the impact of the standard on the Company's population of leases and to evaluate the Company's current accounting policies relating to leases. The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will materially impact the Company's consolidated balance sheet, resulting in current operating lease obligations being reflected on the consolidated balance sheet.
Goodwill (ASU 2017-04)	Eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment loss will instead be measured at the amount by which a reporting unit's carrying value exceeds its fair value,	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements. However, the Company does not expect this ASU to have a significant impact on its financial statements or disclosures.

not to exceed the recorded amount of goodwill. Applied on a prospective basis, with early adoption permitted.

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Inventories

Inventories were as follows:

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

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

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

4. Long-term debt

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

5. Fair value measurements

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

	June 30,			December 31,	
	2018			2017	
	Level	Level	Level	Total	Total
(U.S. Dollars, in thousands)	1	2	3		
Assets					
Collective trust funds	\$—	\$100	\$—	\$100	\$100
Treasury securities	558	—	—	558	556
Equity warrants	—				