Orthofix Medical Inc.
Form 10-K
February 25, 2019
false FY OFIX 0000884624 --12-31 Yes Yes No Large Accelerated Filer false false false In January 2017, the U.S. Securities and Exchange Commission (the “SEC”) approved the Company’s offers of settlement in connection with the SEC’s investigations of accounting matters leading to the Company’s prior restatement of financial statements and the Company’s review of improper payments with respect to its subsidiary in Brazil. Both investigations were initiated in 2013 and involved matters self-reported to the SEC by the Company. The settlements approved by the SEC resolved these two matters, and included payments totaling $14.4 million by the Company to the SEC of amounts previously accrued and funded into escrow by the Company during 2016. In connection with the Brazil-related settlement, the Company agreed to retain an independent compliance consultant for one year to review and test the Company’s compliance program related to the U.S. Foreign Corrupt Practices Act. The Company’s engagement with its independent compliance consultant began in the first quarter of 2017 and concluded in the first quarter of 2018. In addition, in the fourth quarter of 2017 the Company received a favorable insurance settlement of approximately $6 million associated with prior costs incurred related to these matters, which the Company has recognized within general and administrative expenses. P4M P1Y P25Y P33Y P1Y P10Y P3Y P4Y P3Y P7Y P4Y P8Y P4Y6M P4Y6M P4Y6M 0.287 0.306 0.301 0.323 0.0255 0.0107 0.0279 0.0192 P6Y7M9D P6Y7M9D P5Y4M9D 0000884624 2018-01-01 2018-12-31 xbrli:shares 0000884624 2019-02-22 iso4217:USD 0000884624 2018-06-30 0000884624 2018-12-31 0000884624 2017-12-31 iso4217:USD xbrli:shares 0000884624 2017-01-01 2017-12-31 0000884624 2016-01-01 2016-12-31 0000884624 us-gaap:CommonStockMember 2015-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2015-12-31 0000884624 us-gaap:RetainedEarningsMember 2015-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2015-12-31 0000884624 2015-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember us-gaap:AccountingStandardsUpdate201609Member 2016-01-01 2016-12-31 0000884624 us-gaap:RetainedEarningsMember us-gaap:AccountingStandardsUpdate201609Member 2016-01-01 2016-12-31 0000884624 us-gaap:AccountingStandardsUpdate201609Member 2016-01-01 2016-12-31 0000884624 us-gaap:RetainedEarningsMember 2016-01-01 2016-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2016-01-01 2016-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2016-01-01 2016-12-31 0000884624 us-gaap:CommonStockMember 2016-01-01 2016-12-31 0000884624 us-gaap:CommonStockMember 2016-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2016-12-31 0000884624 us-gaap:RetainedEarningsMember 2016-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2016-12-31 0000884624 2016-12-31 0000884624 us-gaap:RetainedEarningsMember 2017-01-01 2017-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2017-01-01 2017-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2017-01-01 2017-12-31 0000884624 us-gaap:CommonStockMember 2017-01-01 2017-12-31 0000884624 us-gaap:CommonStockMember 2017-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2017-12-31 0000884624 us-gaap:RetainedEarningsMember 2017-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2017-12-31 0000884624 us-gaap:RetainedEarningsMember us-gaap:AccountingStandardsUpdate201409Member 2018-01-01 2018-12-31 0000884624 us-gaap:AccountingStandardsUpdate201409Member 2018-01-01 2018-12-31 0000884624 us-gaap:RetainedEarningsMember us-gaap:AccountingStandardsUpdate201616Member 2018-01-01 2018-12-31 0000884624 us-gaap:AccountingStandardsUpdate201616Member 2018-01-01 2018-12-31 0000884624 us-gaap:RetainedEarningsMember 2018-01-01 2018-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2018-01-01 2018-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2018-01-01 2018-12-31 0000884624 us-gaap:CommonStockMember 2018-01-01 2018-12-31 0000884624 us-gaap:CommonStockMember 2018-12-31 0000884624 us-gaap:AdditionalPaidInCapitalMember 2018-12-31 0000884624 us-gaap:RetainedEarningsMember 2018-12-31 0000884624 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2018-12-31 0000884624 us-gaap:FairValueInputsLevel3Member 2018-01-01 2018-12-31 ofix:Segment 0000884624 2018-07-30 2018-07-31 xbrli:pure 0000884624 us-gaap:GeneralAndAdministrativeExpenseMember 2017-01-01 2017-12-31 0000884624 us-gaap:GeneralAndAdministrativeExpenseMember 2016-01-01 2016-12-31 0000884624 srt:MaximumMember

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 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 MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware	98-1340767
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
3451 Plano Parkway,	75056

Lewisville, Texas
(Address of principal executive offices) (Zip Code)
(214) 937-2000

(Registrant's telephone number, including area code)

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

Common Stock, $0.10 par value	Nasdaq Global Select Market
(Title of Class)	(Name of Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	Emerging Growth Company
Non-accelerated filer	Smaller reporting 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 Act). Yes No

The aggregate market value of registrant's common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the fiscal quarter ended June 30, 2018, as reported by the Nasdaq Global

Select Market, was approximately $1,050.4 million.

As of February 22, 2019, 19,061,192 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement to be filed with the Commission in connection with the Orthofix Medical Inc. 2019 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Annual Report.

Orthofix Medical Inc.

Form 10-K for the Year Ended December 31, 2018

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Forward-Looking Statements

This Annual 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," "potent or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A, "Risk Factors". 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, to reflect new information, the occurrence of future events or circumstances or otherwise.

Trademarks

Solely for convenience, our trademarks and trade names in this Annual 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

Item 1. Business

In this Annual Report, the terms "we," "us," "our," "Orthofix," "the Company" and "our Company" refer to the combined operations of Orthofix Medical Inc. (previously Orthofix International N.V.) and its consolidated subsidiaries and affiliates, unless the context requires otherwise.

Company Overview

We are a global medical device company focused on musculoskeletal products and therapies. Our mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, our spine and orthopedic extremities products are distributed in over seventy countries via our sales representatives and distributors.

We have administrative and training facilities in the United States ("U.S."), Italy, Brazil, the United Kingdom ("U.K."), France, and Germany, and manufacturing facilities in the U.S. and Italy. We directly distribute products in the U.S., Italy, the U.K., Germany, and France. In several of these and other markets, we also distribute our products through independent distributors.

On July 31, 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware in accordance with the conversion procedures of the Curaçao Civil Code and the Domestication procedures of Delaware General Corporation Law (the "Domestication"). In connection with the Domestication, we changed our name to "Orthofix Medical Inc." Our shareholders approved and authorized the Domestication at the 2018 Annual General Meeting of Shareholders held on July 17, 2018.

Information regarding shareholder tax consequences of the Domestication and potential tax elections is available on our website under Goverance at www.Orthofix.com. A detailed explanation of the tax consequences of the Domestication is available in the 2018 Proxy Statement, available under Financials & Filings on our website. For additional information, contact us at redomicile@orthofix.com.

YOU SHOULD CONSULT YOUR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL TAX LAWS TO YOUR PARTICLAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. JURISDICTION.

The Company originally was formed in 1987 in Curaçao and is now a corporation operating under the laws of the State of Delaware. Our executive offices are located in Lewisville, Texas.

Available Information and Orthofix Website

Our filings with the Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Annual Proxy Statement on Schedule 14A, any registration statements, and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this Annual Report. Our Internet website is located at www.orthofix.com. Our SEC filings are also available on the SEC website at www.sec.gov.

Business Segments

We manage our business by our four reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation), which accounted for 43%, 20%, 13%, and 24%, respectively, of our total net sales in 2018. The chart below presents net sales, which includes product sales and marketing service fees, by reporting segment for each of the years ended December 31, 2018, 2017, and 2016.

Financial information regarding our reportable business segments and certain geographic information is included in Part II, Item 7 of this Annual Report under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and Note 16 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Bone Growth Therapies

The Bone Growth Therapies reporting segment manufactures, distributes, and provides support services for market-leading bone growth stimulation devices that enhance bone fusion. These class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spinal, appendicular fractures that have not healed (nonunions). These devices utilize Orthofix’s patented pulsed electromagnetic field (“PEMF”) technology, the safety and efficacy of which is supported by basic mechanism of action data in the scientific literature as well as published data from level one randomized controlled clinical trials. The devices are compatible with the STIM onTrack mobile application, which includes a first-to-market feature that enables physicians to remotely view and assess patient adherence to treatment protocols. We currently have research and a clinical study underway to identify potential clinical indications for treating rotator cuff tears. We sell this reporting segment’s products almost exclusively in the U.S. using distributors and direct sales representatives to sell and deliver our devices to hospitals, healthcare providers, and patients.

Bone Growth Therapies Strategy

Our strategy for the Bone Growth Therapies reporting segment is to expand patient access to bone growth therapy devices that deliver noninvasive treatment for promoting healing in fractured bones and spinal fusions. Our key strategies in this segment are:

- Promote competitive advantages of our recently launched products and STIM onTrack mobile app
- Support adoption and reimbursement with:
  - North American Spine Society’s (NASS) Coverage Policy Recommendation
  - Post-market clinical research
- Continue to invest in expanding our sales force
- Bring to market new PEMF products addressing unmet clinical needs

Bone Growth Therapies Products

The following table and discussion identify our principal Bone Growth Therapies products by trade name and describe their primary applications:

Product	Primary Application
CervicalStim Spinal Fusion Therapy	PEMF non-invasive cervical spinal fusion therapy used to enhance bone growth
SpinalStim Spinal Fusion Therapy	PEMF non-invasive lumbar spinal fusion therapy used to enhance bone growth
PhysioStim Bone Healing Therapy	PEMF non-invasive appendicular skeleton healing therapy used to enhance bone growth in nonunion fractures
Spinal Therapy	

Our bone growth therapy devices used in spinal applications are designed to enhance bone growth and the success rate of certain spinal fusions by stimulating the body's own natural healing mechanism post-surgically. These non-invasive portable devices are intended to be used as part of a home treatment program prescribed by a physician.

We offer two spinal fusion therapy devices: the SpinalStim and CervicalStim devices. Our stimulation products use a PEMF technology designed to enhance the growth of bone tissue following surgery and are placed externally over the site to be healed. Research data shows that our PEMF signal induces mineralization and results in a process that stimulates new regeneration at the spinal fusion site. Some spine fusion patients are at greater risk of not achieving a solid fusion of new bone around the fusion site. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a failed fusion or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical bone growth therapy has been shown to significantly increase the probability of fusion success.

The SpinalStim device is a non-invasive spinal fusion stimulator system that has been commercially available in the U.S. since 1990. It is designed for the treatment of the lumbar region of the spine. The device uses proprietary technology and a wavelength to generate a PEMF signal. The U.S. Food and Drug Administration (the "FDA") has approved the SpinalStim system as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion at least nine months post-operatively.

Our CervicalStim product remains the only FDA-approved bone growth stimulator on the market indicated for use as an adjunct to cervical spine fusion surgery in patients at high-risk for non-fusion. The FDA approved this device in 2004, and it has been commercially available in the U.S. since 2005.

In late 2016, the North American Spine Society ("NASS") issued first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of PEMF devices as an adjunct to spinal fusion surgery in high-risk patients. The NASS coverage policy recommends coverage of the use of electrical stimulation for spinal fusion healing in all regions of the spine, including cervical and lumbar regions. The validation of PEMF electrical stimulation from this leading surgical society has and is expected to continue to further support our efforts to expand the availability and use of the therapy to the many patients who can benefit from it.

In January 2017, we announced FDA and European Commission CE mark approval for our next-generation SpinalStim and CervicalStim bone growth stimulators. The CervicalStim and SpinalStim systems available in the U.S. are accompanied by a new application for mobile devices called STIM onTrack. The mobile app includes a first-to-market feature that enables physicians to remotely view how their patients are adhering to prescribed treatment protocols. Designed for use with smartphones and other mobile devices, the STIM onTrack tool helps patients follow their prescription with daily treatment reminders and a device usage calendar. The app is free and available through the iTunes App Store. In addition to the app, the next-generation bone growth stimulators include patient enhancements aimed at improving fit, comfort and ease of use.

Orthopedic Therapy

Our PhysioStim bone healing therapy products use PEMF technology similar to that used in our spine stimulators. The primary difference is that the PhysioStim devices are designed for use on the appendicular skeleton.

A bone's regenerative power results in most fractures healing naturally within a few months. In the presence of certain risk factors, however, some fractures do not heal or heal slowly, resulting in "nonunions." Traditionally, orthopedists have treated such fracture conditions surgically, often by means of a bone graft with fracture fixation devices, such as bone plates, screws or intramedullary rods. These are examples of "invasive" treatments. Our patented PhysioStim bone healing therapy products are designed to use a low level of PEMF signals to noninvasively activate the body's natural healing process. The devices are anatomically designed, allowing ease of placement, patient mobility, and the ability to cover a large treatment area.

In March 2018, we announced the FDA and European Commission CE mark approval for our next-generation PhysioStim bone growth stimulator. Similar to the next-generation CervicalStim and SpinalStim systems, the PhysioStim device is also accompanied by the STIM onTrack mobile app, enabling physicians treating patients with nonunion fractures to remotely view and assess how their patients are adhering to prescribed treatment protocols. In addition to the app, the next-generation PhysioStim devices also include patient enhancements aimed at improving fit, comfort and ease of use.

Future Applications

We have sponsored research at the University of Pennsylvania, Cleveland Clinic, New York University, and University of California San Francisco, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and tendon an efficacy of healing. From these efforts, many studies have been recently published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and differentiation of cells involved in regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic and the University of Pennsylvania, allowing for characterization and visualization of the Orthofix PEMF waveform, is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data, along with additional clinical data, could represent new clinical indication opportunities for our regenerative stimulation solutions.

Spinal Implants

The Spinal Implants reporting segment designs, develops and markets a portfolio of motion preservation and implant products used in surgical procedures of the spine. We distribute these products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

Spinal Implants Strategy

Our vision for the Spinal Implants reporting segment is to become a first choice for our distributors and surgeons by demonstrating strength in partnership. Our key strategies in this segment are:

- Execute controlled, limited market launch and extensive training curriculum in the U.S. for our M6-C artificial cervical disc
- Continue the strong pace of new product launches
- Provide exceptional training and education programs for sales representatives and surgeons
- Acquire or license products, technologies and companies to further expand the spinal implants portfolio

Spinal Implants Products

The following table and discussion identify our key Spinal Implants products by trade name and describe their primary applications:

Product	Primary Application
M6-C Artificial Cervical Disc	A next-generation artificial disc developed to replace an intervertebral disc damaged by cervical disc degeneration; the only artificial cervical disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into its design
M6-L Artificial Lumbar Disc	A next-generation artificial disc developed to replace an intervertebral disc damaged by lumbar disc degeneration; the only artificial lumbar disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into its design

Product	Primary Application
FORZA XP Expandable Spacer System	A titanium expandable spacer system for Posterior Lumbar Interbody Fusion (“PLIF”) and Transforaminal Lumbar Interbody Fusion (“TLIF”) procedures featuring a large graft window with the ability to pack post expansion in situ
CETRA Anterior Cervical Plate System	An anterior cervical plate system offering a low profile plate with an intuitive locking mechanism, large graft windows, a high degree of screw angulation and simplified instrumentation
CONSTRUX Mini PEEK / Titanium Composite (“PTC”) Spacer System	A cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a Polyetheretherketones (“PEEK”) core to maintain imaging characteristics
FORZA PTC Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics