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

2018-01-01 2018-12-31 0000884624 srt:MaximumMember 2017-01-01 2017-12-31 0000884624
srt:MaximumMember 2016-01-01 2016-12-31 0000884624 srt:EuropeMember 2018-01-01 2018-12-31 0000884624
ofix:MusculoskeletalTransplantFoundationMember 2018-01-01 2018-12-31 0000884624
ofix:MusculoskeletalTransplantFoundationMember 2017-01-01 2017-12-31 0000884624
ofix:MusculoskeletalTransplantFoundationMember 2016-01-01 2016-12-31 0000884624 ofix:SpinalKineticsMember
2018-12-31 0000884624 ofix:AccountingStandardsUpdate201601And201803Member 2018-01-01 2018-03-31
0000884624 ofix:AccountingStandardsUpdate201601And201803Member 2018-07-01 2018-09-30 0000884624
2017-07-01 2017-12-31 ofix:Asset 0000884624 us-gaap:AccountingStandardsUpdate201616Member 2018-01-01
2018-01-01 0000884624 us-gaap:AccountingStandardsUpdate201618Member 2018-01-01 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201618Member 2017-01-01 2017-12-31 0000884624
us-gaap:AccountingStandardsUpdate201618Member 2016-01-01 2016-12-31 0000884624
us-gaap:AccountingStandardsUpdate201701Member 2018-01-01 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201602Member us-gaap:SubsequentEventMember 2019-01-01 0000884624
ofix:AccountingStandardsUpdate201802Member us-gaap:ScenarioForecastMember 2019-01-01 2019-01-01
0000884624 ofix:SpinalKineticsMember 2018-04-30 2018-04-30 0000884624 srt:MaximumMember
ofix:SpinalKineticsMember 2018-04-30 0000884624 ofix:SpinalKineticsMember 2018-03-15 0000884624
ofix:SpinalKineticsMember 2018-01-01 2018-12-31 0000884624 ofix:SpinalKineticsMember 2018-04-30
0000884624 ofix:SpinalKineticsMember 2018-05-01 2018-12-31 0000884624
ofix:USFoodAndDrugAdministrationMember ofix:SpinalKineticsMember 2018-04-30 0000884624
ofix:RevenueMilestoneMember ofix:SpinalKineticsMember 2018-04-30 0000884624
us-gaap:OperatingExpenseMember ofix:SpinalKineticsMember 2018-05-01 2018-12-31 0000884624
ofix:DevelopedTechnologyMember ofix:SpinalKineticsMember 2018-04-30 0000884624
ofix:DevelopedTechnologyMember ofix:SpinalKineticsMember 2018-12-31 0000884624
ofix:TrademarksFiniteLivedMember ofix:SpinalKineticsMember 2018-04-30 0000884624
ofix:TrademarksFiniteLivedMember ofix:SpinalKineticsMember 2018-12-31 0000884624
ofix:DevelopedTechnologyMember ofix:SpinalKineticsMember 2018-01-01 2018-12-31 0000884624
ofix:TrademarksFiniteLivedMember ofix:SpinalKineticsMember 2018-01-01 2018-12-31 0000884624
ofix:SpinalKineticsMember ofix:SpinalImplantsMember 2018-12-31 0000884624 ofix:SpinalKineticsMember
2017-01-01 2017-12-31 0000884624 us-gaap:BuildingMember srt:MinimumMember 2018-01-01 2018-12-31
0000884624 us-gaap:BuildingMember srt:MaximumMember 2018-01-01 2018-12-31 0000884624
us-gaap:EquipmentMember srt:MinimumMember 2018-01-01 2018-12-31 0000884624 us-gaap:EquipmentMember
srt:MaximumMember 2018-01-01 2018-12-31 0000884624 ofix:InstrumentationMember srt:MinimumMember
2018-01-01 2018-12-31 0000884624 ofix:InstrumentationMember srt:MaximumMember 2018-01-01 2018-12-31
0000884624 us-gaap:ComputerEquipmentMember srt:MinimumMember 2018-01-01 2018-12-31 0000884624
us-gaap:ComputerEquipmentMember srt:MaximumMember 2018-01-01 2018-12-31 0000884624
us-gaap:FurnitureAndFixturesMember srt:MinimumMember 2018-01-01 2018-12-31 0000884624
us-gaap:FurnitureAndFixturesMember srt:MaximumMember 2018-01-01 2018-12-31 0000884624
us-gaap:BuildingMember 2018-12-31 0000884624 us-gaap:BuildingMember 2017-12-31 0000884624
ofix:PlantAndEquipmentMember 2018-12-31 0000884624 ofix:PlantAndEquipmentMember 2017-12-31 0000884624
ofix:InstrumentationMember 2018-12-31 0000884624 ofix:InstrumentationMember 2017-12-31 0000884624
ofix:ComputerSoftwareMember 2018-12-31 0000884624 ofix:ComputerSoftwareMember 2017-12-31 0000884624
us-gaap:FurnitureAndFixturesMember 2018-12-31 0000884624 us-gaap:FurnitureAndFixturesMember 2017-12-31
0000884624 us-gaap:ConstructionInProgressMember 2018-12-31 0000884624
us-gaap:ConstructionInProgressMember 2017-12-31 0000884624 us-gaap:PatentsMember 2018-12-31 0000884624
us-gaap:PatentsMember 2017-12-31 0000884624 ofix:DevelopedTechnologyMember 2018-12-31 0000884624
ofix:IndefiniteInProcessResearchAndDevelopmentMember 2018-12-31 0000884624
ofix:LicensingAgreementsAndOtherMember 2018-12-31 0000884624 ofix:LicensingAgreementsAndOtherMember
2017-12-31 0000884624 ofix:TrademarksFiniteLivedMember 2018-12-31 0000884624
ofix:TrademarksFiniteLivedMember 2017-12-31 0000884624 us-gaap:PatentsMember 2018-01-01 2018-12-31
0000884624 ofix:DevelopedTechnologyMember 2018-01-01 2018-12-31 0000884624
ofix:IndefiniteInProcessResearchAndDevelopmentMember 2018-01-01 2018-12-31 0000884624

ofix:LicensingAgreementsAndOtherMember 2018-01-01 2018-12-31 0000884624
ofix:TrademarksFiniteLivedMember 2018-01-01 2018-12-31 0000884624
us-gaap:InProcessResearchAndDevelopmentMember us-gaap:ScenarioForecastMember 2019-02-01 2019-02-28
0000884624 ofix:BoneGrowthTherapiesMember 2017-12-31 0000884624 ofix:BiologicsMember 2017-12-31
0000884624 ofix:SpinalImplantsMember ofix:SpinalKineticsMember 2018-01-01 2018-12-31 0000884624
ofix:BoneGrowthTherapiesMember 2018-12-31 0000884624 ofix:SpinalImplantsMember 2018-12-31 0000884624
ofix:BiologicsMember 2018-12-31 0000884624 ofix:ENeuraNoteMember ofix:ENeuraIncMember 2015-03-03
2015-03-04 0000884624 ofix:ENeuraNoteMember ofix:ENeuraIncMember
us-gaap:ConvertibleDebtSecuritiesMember 2015-03-04 0000884624 ofix:ENeuraNoteMember
ofix:ENeuraIncMember 2015-03-04 0000884624 ofix:ENeuraNoteMember ofix:ENeuraIncMember 2018-01-01
2018-12-31 0000884624 ofix:ENeuraNoteMember ofix:ENeuraIncMember srt:MinimumMember 2018-12-31
0000884624 ofix:ENeuraNoteMember ofix:ENeuraIncMember us-gaap:PreferredStockMember 2018-12-31
0000884624 ofix:BoneBiologicsIncMember 2018-12-31 0000884624 ofix:BoneBiologicsIncMember 2018-01-01
2018-12-31 0000884624 us-gaap:CommonStockMember ofix:BoneBiologicsIncMember 2018-01-01 2018-03-31
0000884624 ofix:BoneBiologicsIncMember 2018-01-01 2018-03-31 0000884624
us-gaap:AccountingStandardsUpdate201601Member ofix:CommonStockAndWarrantsMember
ofix:BoneBiologicsIncMember 2018-07-01 2018-09-30 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2018-01-01 2018-12-31 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2017-01-01 2017-12-31 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2016-01-01 2016-12-31 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2017-12-31 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2016-12-31 0000884624
ofix:ExtremityFixationRestructuringPlanMember 2018-12-31 0000884624 us-gaap:OperatingExpenseMember
ofix:USRestructuringPlanMember 2017-01-01 2017-12-31 0000884624 ofix:USRestructuringPlanMember
2018-01-01 2018-12-31 0000884624 ofix:USRestructuringPlanMember 2017-01-01 2017-12-31 0000884624
ofix:USRestructuringPlanMember 2017-12-31 0000884624 ofix:TwoThousandFifteenCreditAgreementMember
us-gaap:RevolvingCreditFacilityMember 2018-01-01 2018-12-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember 2015-08-31
0000884624 ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
2018-12-31 0000884624 ofix:TwoThousandFifteenCreditAgreementMember
us-gaap:RevolvingCreditFacilityMember srt:MaximumMember 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
us-gaap:LondonInterbankOfferedRateLIBORMember srt:MinimumMember 2015-08-29 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
us-gaap:LondonInterbankOfferedRateLIBORMember srt:MaximumMember 2015-08-29 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
us-gaap:BaseRateMember srt:MinimumMember 2015-08-29 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
us-gaap:BaseRateMember srt:MaximumMember 2015-08-29 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember srt:MinimumMember
2015-08-29 2015-08-31 0000884624 ofix:TwoThousandFifteenCreditAgreementMember
us-gaap:RevolvingCreditFacilityMember srt:MaximumMember 2015-08-29 2015-08-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember 2015-08-29 2015-08-30
0000884624 ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
2017-12-31 0000884624 ofix:TwoThousandFifteenCreditAgreementMember
us-gaap:RevolvingCreditFacilityMember 2016-01-01 2016-12-31 0000884624
ofix:TwoThousandFifteenCreditAgreementMember us-gaap:RevolvingCreditFacilityMember 2017-01-01 2017-12-31
0000884624 ofix:FirstAmendedAndRestatedCreditAgreementMember us-gaap:RevolvingCreditFacilityMember
2018-07-31 iso4217:EUR 0000884624 country:IT 2018-12-31 0000884624 country:IT 2017-12-31 0000884624
us-gaap:FairValueMeasurementsRecurringMember ofix:TreasurySecuritiesMember 2018-12-31 0000884624
us-gaap:FairValueInputsLevel1Member us-gaap:FairValueMeasurementsRecurringMember

ofix:TreasurySecuritiesMember 2018-12-31 0000884624 us-gaap:FairValueMeasurementsRecurringMember
us-gaap:EquitySecuritiesMember 2018-12-31 0000884624 us-gaap:FairValueInputsLevel2Member
us-gaap:FairValueMeasurementsRecurringMember us-gaap:EquitySecuritiesMember 2018-12-31 0000884624
us-gaap:FairValueMeasurementsRecurringMember us-gaap:DebtSecuritiesMember 2018-12-31 0000884624
us-gaap:FairValueInputsLevel3Member us-gaap:FairValueMeasurementsRecurringMember
us-gaap:DebtSecuritiesMember 2018-12-31 0000884624 us-gaap:FairValueMeasurementsRecurringMember
2018-12-31 0000884624 us-gaap:FairValueInputsLevel1Member us-gaap:FairValueMeasurementsRecurringMember
2018-12-31 0000884624 us-gaap:FairValueInputsLevel2Member us-gaap:FairValueMeasurementsRecurringMember
2018-12-31 0000884624 us-gaap:FairValueInputsLevel3Member us-gaap:FairValueMeasurementsRecurringMember
2018-12-31 0000884624 us-gaap:FairValueMeasurementsRecurringMember ofix:CollectiveTrustFundsMember
2017-12-31 0000884624 us-gaap:FairValueInputsLevel2Member us-gaap:FairValueMeasurementsRecurringMember
ofix:CollectiveTrustFundsMember 2017-12-31 0000884624 us-gaap:FairValueMeasurementsRecurringMember
ofix:TreasurySecuritiesMember 2017-12-31 0000884624 us-gaap:FairValueInputsLevel1Member
us-gaap:FairValueMeasurementsRecurringMember ofix:TreasurySecuritiesMember 2017-12-31 0000884624
us-gaap:FairValueMeasurementsRecurringMember us-gaap:DebtSecuritiesMember 2017-12-31 0000884624
us-gaap:FairValueInputsLevel3Member us-gaap:FairValueMeasurementsRecurringMember
us-gaap:DebtSecuritiesMember 2017-12-31 0000884624 us-gaap:FairValueMeasurementsRecurringMember
2017-12-31 0000884624 us-gaap:FairValueInputsLevel1Member us-gaap:FairValueMeasurementsRecurringMember
2017-12-31 0000884624 us-gaap:FairValueInputsLevel2Member us-gaap:FairValueMeasurementsRecurringMember
2017-12-31 0000884624 us-gaap:FairValueInputsLevel3Member us-gaap:FairValueMeasurementsRecurringMember
2017-12-31 0000884624 us-gaap:CommonStockMember 2018-01-01 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201601Member 2018-01-01 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201601Member 2017-01-01 2017-12-31 0000884624
us-gaap:AccountingStandardsUpdate201601Member 2016-01-01 2016-12-31 0000884624
us-gaap:DebtSecuritiesMember us-gaap:FairValueInputsLevel3Member 2018-12-31 0000884624
us-gaap:DebtSecuritiesMember us-gaap:FairValueInputsLevel3Member 2018-01-01 2018-12-31 0000884624
us-gaap:DebtSecuritiesMember us-gaap:FairValueInputsLevel3Member 2017-12-31 0000884624
us-gaap:DebtSecuritiesMember us-gaap:FairValueInputsLevel3Member 2016-12-31 0000884624
us-gaap:DebtSecuritiesMember us-gaap:FairValueInputsLevel3Member 2017-01-01 2017-12-31 0000884624
us-gaap:OtherCurrentLiabilitiesMember ofix:SpinalKineticsMember 2018-12-31 0000884624
us-gaap:OtherNoncurrentLiabilitiesMember ofix:SpinalKineticsMember 2018-12-31 0000884624
us-gaap:FairValueInputsLevel3Member 2018-12-31 0000884624 us-gaap:SubsequentEventMember
ofix:SpinalKineticsMember ofix:USFoodAndDrugAdministrationMember 2019-02-06 0000884624
us-gaap:SubsequentEventMember ofix:SpinalKineticsMember ofix:USFoodAndDrugAdministrationMember
2019-02-14 2019-02-14 0000884624 ofix:SpinalKineticsMember us-gaap:OperatingExpenseMember 2018-01-01
2018-12-31 0000884624 us-gaap:ScenarioForecastMember 2019-01-01 2019-03-31 0000884624 2017-01-01
2017-01-31 0000884624 2017-10-01 2017-12-31 0000884624 2018-07-31 0000884624 2015-08-31 0000884624
us-gaap:AccumulatedTranslationAdjustmentMember 2016-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember 2016-12-31 0000884624
us-gaap:AccumulatedTranslationAdjustmentMember 2017-01-01 2017-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember 2017-01-01 2017-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember
us-gaap:ReclassificationOutOfAccumulatedOtherComprehensiveIncomeMember 2017-01-01 2017-12-31
0000884624 us-gaap:ReclassificationOutOfAccumulatedOtherComprehensiveIncomeMember 2017-01-01
2017-12-31 0000884624 us-gaap:AccumulatedTranslationAdjustmentMember 2017-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember 2017-12-31 0000884624
us-gaap:AccumulatedTranslationAdjustmentMember 2018-01-01 2018-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember 2018-01-01 2018-12-31 0000884624
us-gaap:AccumulatedTranslationAdjustmentMember 2018-12-31 0000884624
us-gaap:AccumulatedNetUnrealizedInvestmentGainLossMember 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201409Member 2018-01-01 0000884624

us-gaap:CalculatedUnderRevenueGuidanceInEffectBeforeTopic606Member 2017-12-31 0000884624
us-gaap:DifferenceBetweenRevenueGuidanceInEffectBeforeAndAfterTopic606Member 2017-12-31 0000884624
us-gaap:AccountingStandardsUpdate201409Member
us-gaap:CalculatedUnderRevenueGuidanceInEffectBeforeTopic606Member 2018-01-01 2018-12-31 0000884624
us-gaap:AccountingStandardsUpdate201409Member
us-gaap:DifferenceBetweenRevenueGuidanceInEffectBeforeAndAfterTopic606Member 2018-01-01 2018-12-31
0000884624 ofix:BiologicsMember 2018-01-01 2018-12-31 0000884624 us-gaap:ShippingAndHandlingMember
2018-01-01 2018-12-31 0000884624 us-gaap:ShippingAndHandlingMember 2017-01-01 2017-12-31 0000884624
us-gaap:ShippingAndHandlingMember 2016-01-01 2016-12-31 0000884624 us-gaap:OtherNoncurrentAssetsMember
2018-12-31 0000884624 us-gaap:OtherNoncurrentAssetsMember 2017-12-31 0000884624
ofix:OtherContractAssetsMember 2018-01-01 2018-12-31 0000884624 ofix:OtherContractAssetsMember 2017-01-01
2017-12-31 0000884624 ofix:BoneGrowthTherapiesMember 2018-01-01 2018-12-31 0000884624
ofix:SpinalImplantsMember 2018-01-01 2018-12-31 0000884624 ofix:OrthofixExtremitiesMember 2018-01-01
2018-12-31 0000884624 ofix:BoneGrowthTherapiesMember 2017-01-01 2017-12-31 0000884624
ofix:SpinalImplantsMember 2017-01-01 2017-12-31 0000884624 ofix:BiologicsMember 2017-01-01 2017-12-31
0000884624 ofix:OrthofixExtremitiesMember 2017-01-01 2017-12-31 0000884624
ofix:BoneGrowthTherapiesMember 2016-01-01 2016-12-31 0000884624 ofix:SpinalImplantsMember 2016-01-01
2016-12-31 0000884624 ofix:BiologicsMember 2016-01-01 2016-12-31 0000884624
ofix:OrthofixExtremitiesMember 2016-01-01 2016-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BoneGrowthTherapiesMember 2018-01-01 2018-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BoneGrowthTherapiesMember 2017-01-01 2017-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BoneGrowthTherapiesMember 2016-01-01 2016-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:SpinalImplantsMember 2018-01-01 2018-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:SpinalImplantsMember 2017-01-01 2017-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:SpinalImplantsMember 2016-01-01 2016-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BiologicsMember 2018-01-01 2018-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BiologicsMember 2017-01-01 2017-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:BiologicsMember 2016-01-01 2016-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:OrthofixExtremitiesMember 2018-01-01 2018-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:OrthofixExtremitiesMember 2017-01-01 2017-12-31 0000884624 us-gaap:OperatingSegmentsMember
ofix:OrthofixExtremitiesMember 2016-01-01 2016-12-31 0000884624 us-gaap:CorporateNonSegmentMember
2018-01-01 2018-12-31 0000884624 us-gaap:CorporateNonSegmentMember 2017-01-01 2017-12-31 0000884624
us-gaap:CorporateNonSegmentMember 2016-01-01 2016-12-31 0000884624
us-gaap:MaterialReconcilingItemsMember 2018-01-01 2018-12-31 0000884624
us-gaap:MaterialReconcilingItemsMember 2017-01-01 2017-12-31 0000884624
us-gaap:MaterialReconcilingItemsMember 2016-01-01 2016-12-31 0000884624 country:US 2018-01-01 2018-12-31
0000884624 country:US 2017-01-01 2017-12-31 0000884624 country:US 2016-01-01 2016-12-31 0000884624
country:IT 2018-01-01 2018-12-31 0000884624 country:IT 2017-01-01 2017-12-31 0000884624 country:IT
2016-01-01 2016-12-31 0000884624 stpr:DE 2018-01-01 2018-12-31 0000884624 stpr:DE 2017-01-01 2017-12-31
0000884624 stpr:DE 2016-01-01 2016-12-31 0000884624 country:GB 2018-01-01 2018-12-31 0000884624
country:GB 2017-01-01 2017-12-31 0000884624 country:GB 2016-01-01 2016-12-31 0000884624 country:BR
2018-01-01 2018-12-31 0000884624 country:BR 2017-01-01 2017-12-31 0000884624 country:BR 2016-01-01
2016-12-31 0000884624 ofix:OtherCountriesMember 2018-01-01 2018-12-31 0000884624
ofix:OtherCountriesMember 2017-01-01 2017-12-31 0000884624 ofix:OtherCountriesMember 2016-01-01
2016-12-31 0000884624 country:US ofix:BoneGrowthTherapiesMember 2018-01-01 2018-12-31 0000884624
country:US ofix:BoneGrowthTherapiesMember 2017-01-01 2017-12-31 0000884624 country:US
ofix:BoneGrowthTherapiesMember 2016-01-01 2016-12-31 0000884624 us-gaap:NonUsMember
ofix:BoneGrowthTherapiesMember 2018-01-01 2018-12-31 0000884624 us-gaap:NonUsMember
ofix:BoneGrowthTherapiesMember 2017-01-01 2017-12-31 0000884624 us-gaap:NonUsMember
ofix:BoneGrowthTherapiesMember 2016-01-01 2016-12-31 0000884624 country:US ofix:SpinalImplantsMember
2018-01-01 2018-12-31 0000884624 country:US ofix:SpinalImplantsMember 2017-01-01 2017-12-31 0000884624

country:US ofix:SpinalImplantsMember 2016-01-01 2016-12-31 0000884624 us-gaap:NonUsMember
ofix:SpinalImplantsMember 2018-01-01 2018-12-31 0000884624 us-gaap:NonUsMember
ofix:SpinalImplantsMember 2017-01-01 2017-12-31 0000884624 us-gaap:NonUsMember
ofix:SpinalImplantsMember 2016-01-01 2016-12-31 0000884624 country:US ofix:BiologicsMember 2018-01-01
2018-12-31 0000884624 country:US ofix:BiologicsMember 2017-01-01 2017-12-31 0000884624 country:US
ofix:BiologicsMember 2016-01-01 2016-12-31 0000884624 us-gaap:NonUsMember ofix:BiologicsMember
2018-01-01 2018-12-31 0000884624 us-gaap:NonUsMember ofix:BiologicsMember 2017-01-01 2017-12-31
0000884624 us-gaap:NonUsMember ofix:BiologicsMember 2016-01-01 2016-12-31 0000884624 country:US
ofix:OrthofixExtremitiesMember 2018-01-01 2018-12-31 0000884624 country:US ofix:OrthofixExtremitiesMember
2017-01-01 2017-12-31 0000884624 country:US ofix:OrthofixExtremitiesMember 2016-01-01 2016-12-31
0000884624 us-gaap:NonUsMember ofix:OrthofixExtremitiesMember 2018-01-01 2018-12-31 0000884624
us-gaap:NonUsMember ofix:OrthofixExtremitiesMember 2017-01-01 2017-12-31 0000884624
us-gaap:NonUsMember ofix:OrthofixExtremitiesMember 2016-01-01 2016-12-31 0000884624
us-gaap:NonUsMember 2018-01-01 2018-12-31 0000884624 us-gaap:NonUsMember 2017-01-01 2017-12-31
0000884624 us-gaap:NonUsMember 2016-01-01 2016-12-31 0000884624 country:US 2018-12-31 0000884624
country:US 2017-12-31 0000884624 stpr:DE 2018-12-31 0000884624 stpr:DE 2017-12-31 0000884624 country:GB
2018-12-31 0000884624 country:GB 2017-12-31 0000884624 country:BR 2018-12-31 0000884624 country:BR
2017-12-31 0000884624 ofix:OtherCountriesMember 2018-12-31 0000884624 ofix:OtherCountriesMember
2017-12-31 0000884624 ofix:TwoThousandTwelveLongTermIncentivePlanMember 2018-01-01 2018-12-31
0000884624 ofix:TwoThousandTwelveLongTermIncentivePlanMember 2018-12-31 0000884624
us-gaap:RestrictedStockMember ofix:TwoThousandTwelveLongTermIncentivePlanMember 2018-12-31 0000884624
us-gaap:RestrictedStockUnitsRSUMember ofix:TwoThousandTwelveLongTermIncentivePlanMember 2018-12-31
0000884624 ofix:LongTermIncentivePlanMember 2004-06-29 0000884624 ofix:StaffShareOptionPlanMember
ofix:LongTermIncentivePlanMember 2018-12-31 0000884624 ofix:SpinalKineticsInducementPlanMember
2018-12-31 0000884624 ofix:SpinalKineticsInducementPlanMember us-gaap:RestrictedStockMember 2018-12-31
0000884624 ofix:EmployeeStockPurchasePlanMember srt:MinimumMember 2018-12-31 0000884624
ofix:EmployeeStockPurchasePlanMember 2018-12-31 0000884624 ofix:EmployeeStockPurchasePlanMember
2018-01-01 2018-12-31 0000884624 us-gaap:CostOfSalesMember 2018-01-01 2018-12-31 0000884624
us-gaap:CostOfSalesMember 2017-01-01 2017-12-31 0000884624 us-gaap:CostOfSalesMember 2016-01-01
2016-12-31 0000884624 us-gaap:SellingAndMarketingExpenseMember 2018-01-01 2018-12-31 0000884624
us-gaap:SellingAndMarketingExpenseMember 2017-01-01 2017-12-31 0000884624
us-gaap:SellingAndMarketingExpenseMember 2016-01-01 2016-12-31 0000884624
us-gaap:GeneralAndAdministrativeExpenseMember 2018-01-01 2018-12-31 0000884624
us-gaap:ResearchAndDevelopmentExpenseMember 2018-01-01 2018-12-31 0000884624
us-gaap:ResearchAndDevelopmentExpenseMember 2017-01-01 2017-12-31 0000884624
us-gaap:ResearchAndDevelopmentExpenseMember 2016-01-01 2016-12-31 0000884624
us-gaap:EmployeeStockOptionMember 2018-01-01 2018-12-31 0000884624 us-gaap:EmployeeStockOptionMember
2017-01-01 2017-12-31 0000884624 us-gaap:EmployeeStockOptionMember 2016-01-01 2016-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2018-01-01 2018-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2017-01-01 2017-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2016-01-01 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsAndStockUnitsMember 2018-01-01 2018-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsAndStockUnitsMember 2017-01-01 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsAndStockUnitsMember 2016-01-01 2016-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember 2018-01-01 2018-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember 2017-01-01 2017-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember 2016-01-01 2016-12-31 0000884624 us-gaap:EmployeeStockMember
2018-01-01 2018-12-31 0000884624 us-gaap:EmployeeStockMember 2017-01-01 2017-12-31 0000884624
us-gaap:EmployeeStockMember 2016-01-01 2016-12-31 0000884624 us-gaap:EmployeeStockOptionMember
2018-12-31 0000884624 us-gaap:EmployeeStockOptionMember 2017-12-31 0000884624
us-gaap:EmployeeStockOptionMember 2016-12-31 0000884624

ofix:RestrictedStockUnitWithDeferredDeliveryMember 2018-01-01 2018-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2018-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2017-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndStockUnitsMember 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2015-01-01 2015-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2018-01-01 2018-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2017-01-01 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2016-01-01 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2018-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsMember 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2015-01-01 2015-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2018-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2018-01-01 2018-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2017-01-01 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2016-01-01 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockUnitsMember 2016-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember srt:MinimumMember 2018-01-01 2018-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember srt:MaximumMember 2018-01-01 2018-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember ofix:AprilTwoThousandEighteenGrantDateMember 2018-01-01
2018-12-31 0000884624 ofix:MarketBasedRestrictedStockUnitMember
ofix:JulyTwoThousandSeventeenGrantDateMember 2018-01-01 2018-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember ofix:JulyTwoThousandSixteenGrantDateMember 2018-01-01
2018-12-31 0000884624 ofix:MarketBasedRestrictedStockUnitMember 2018-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember 2017-12-31 0000884624
ofix:MarketBasedRestrictedStockUnitMember 2016-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsAndStockUnitsMember 2017-12-31 0000884624
ofix:PerformanceBasedRestrictedStockAwardsAndStockUnitsMember 2018-12-31 0000884624 country:US
2018-01-01 2018-12-31 0000884624 country:US 2017-01-01 2017-12-31 0000884624 country:US 2016-01-01
2016-12-31 0000884624 country:IT 2018-01-01 2018-12-31 0000884624
us-gaap:WorkforceSubjectToCollectiveBargainingArrangementsMember
us-gaap:LaborForceConcentrationRiskMember country:IT 2018-01-01 2018-12-31 0000884624 2018-01-01
2018-03-31 0000884624 us-gaap:StateAndLocalJurisdictionMember 2018-12-31 0000884624
us-gaap:ForeignCountryMember 2018-12-31 0000884624 us-gaap:StateAndLocalJurisdictionMember
ofix:SpinalKineticsMember 2018-12-31 0000884624 us-gaap:DomesticCountryMember 2018-12-31 0000884624
srt:MinimumMember 2018-12-31 0000884624 srt:MaximumMember 2018-12-31 0000884624
us-gaap:ScenarioForecastMember 2019-01-01 2019-12-31 0000884624
ofix:StockOptionsAndEmployeeStockPurchasePlanMember 2018-01-01 2018-12-31 0000884624
ofix:StockOptionsAndEmployeeStockPurchasePlanMember 2017-01-01 2017-12-31 0000884624
ofix:StockOptionsAndEmployeeStockPurchasePlanMember 2016-01-01 2016-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndUnitsMember 2017-01-01 2017-12-31 0000884624
ofix:TimeBasedRestrictedStockAwardsAndUnitsMember 2016-01-01 2016-12-31 0000884624
ofix:RestrictedStockAndPerformanceBasedEquityAwardsMember us-gaap:EmployeeStockOptionMember
2018-01-01 2018-12-31 0000884624 ofix:RestrictedStockAndPerformanceBasedEquityAwardsMember
us-gaap:EmployeeStockOptionMember 2017-01-01 2017-12-31 0000884624
ofix:RestrictedStockAndPerformanceBasedEquityAwardsMember us-gaap:EmployeeStockOptionMember
2016-01-01 2016-12-31 0000884624 2018-04-01 2018-06-30 0000884624 2018-07-01 2018-09-30 0000884624
2018-10-01 2018-12-31 0000884624 srt:MaximumMember 2018-01-01 2018-03-31 0000884624
srt:MaximumMember 2018-04-01 2018-06-30 0000884624 srt:MaximumMember 2018-07-01 2018-09-30
0000884624 2017-01-01 2017-03-31 0000884624 2017-04-01 2017-06-30 0000884624 2017-07-01 2017-09-30

0000884624 us-gaap:SubsequentEventMember 2019-01-31 2019-01-31 0000884624
us-gaap:SubsequentEventMember ofix:OptionsMedicalFounderMember 2019-01-31 2019-01-31 0000884624
ofix:PresidentAndChiefExecutiveOfficerMember us-gaap:SubsequentEventMember
ofix:RetirementAgreementMember 2019-02-25 0000884624 ofix:PresidentAndChiefExecutiveOfficerMember
us-gaap:SubsequentEventMember ofix:RetirementAgreementMember 2019-02-25 2019-02-25

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

Table of Contents

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 |
| PILLAR SA PTC PEEK Spacer System | A standalone Anterior Lumbar Interbody Fusion (“ALIF”) lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics |
| FIREBIRD / FIREBIRD NXG Spinal Fixation System | A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure |
| JANUS Midline Fixation Screw | An addition to the Firebird Spinal Fixation System designed to achieve more cortical bone purchase in the medial to lateral trajectory when compared to traditional pedicle screws and provides surgeons with the option of a midline approach |
| Connector System for revisions | A comprehensive system to reduce the complexity of revising and extending existing spinal constructs; this eliminates the need to remove existing hardware while providing stability at adjacent levels |
| CENTURION Posterior Occipital Cervico-Thoracic (“POCT”) System | A multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome that allow the surgeon to build a spinal implant construct |
| SAMBA-SCREW System | A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients |
| FIREBIRD Deformity Correction System | An extension to the Firebird Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures |
| PHOENIX Minimally Invasive Spinal Fixation System | A multi-axial extended reduction screw body used with the Firebird Spinal Fixation System designed to be implanted during a posterior thoracolumbar spine fusion procedure |
| LONESTAR Cervical Stand Alone (“CSA”) | A stand-alone spacer system designed to provide the biomechanical strength to a traditional or minimal invasive Anterior Cervical Discectomy and Fusion |

| | |
|---|---|
| | (“ACDF”) procedure with less disruption of patient anatomy and to preserve the anatomical profile |
| SKYHAWK Lateral Interbody Fusion System & Lateral Plate System | Provides a complete solution for the surgeon to perform a Lateral Lumbar Interbody Fusion, an approach to spinal fusion in which the surgeon accesses the intervertebral disc space using a surgical approach from the patient’s side that disturbs fewer structures and tissues |
| FORZA Spacer System | PEEK interbody devices for PLIF and TLIF procedures |

Motion Preservation Solutions

On April 30, 2018, we acquired Spinal Kinetics Inc., a privately held developer and manufacturer of artificial cervical and lumbar discs, namely the M6-C Cervical and M6-L Lumbar Artificial Discs, which are used to treat patients suffering from degenerative disc disease of the spine. The M6 discs are the only artificial discs that mimic the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into their design. Like a natural disc, this unique construct allows for shock absorption at the implanted level, as well as provides a controlled range of motion when the spine transitions in its combined complex movements. Both discs have European Commission CE mark approval and historically have been exclusively distributed outside the U.S. On February 6, 2019, we received FDA approval of the M6-C Artificial Cervical Disc to treat patients with cervical disc degeneration. We expect to release the M6-C Artificial Cervical Disc in 2019 in the U.S. through a controlled, limited market launch accompanied by an extensive training and education curriculum for surgeons.

Spinal Repair Solutions

We provide a wide array of implants designed for use primarily in cervical, thoracic and lumbar fusion surgeries. These implants are made of either metal or a thermoplastic compound called PEEK. The majority of the implants that we offer are made of titanium metal. This includes the Cetra, 3°, Reliant and Hallmark cervical plates. Additionally, the Spinal Fixation System, the Firebird Spinal Fixation System, the Phoenix Minimally Invasive Spinal Fixation System, the Ascent, Ascent LE, and the Centurion POCT Systems are sets of rods, cross connectors and screws that are implanted during posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation Systems are designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our product ProView MAP System. To complement our plates, rods and screw fixation options we offer an entire portfolio of cervical and thoracolumbar PEEK interbody devices within our Pillar and Forza product lines. This interbody portfolio includes two stand-alone devices, Lonestar and Pillar SA, as well as the Construx Mini PTC system, a novel titanium composite spacer which offers a superior alternative to other plasma spray coated options currently available on the market. We also offer specialty plates and screws that are used in less common procedures, and as such, are not manufactured by many device makers.

Biologics

The Biologics reporting segment provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This reporting segment specializes in the marketing of regeneration tissue forms and distributes MTF Biologics (“MTF”) tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives. Our partnership with MTF allows us to exclusively market the Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Biologics Strategy

In order to drive further adoption and use of our products, our strategy for the Biologics reporting segment is to educate physicians, both directly and through our sales force, of the surgical and patient benefits of using our portfolio of regenerative tissues and products to augment their surgical procedures and results. Our key strategies in this segment are:

- Expand sales force coverage in the spine market and continue to expand into other orthopedic procedures

- Continue to leverage the surgeon-preferred Trinity ELITE characteristics and clinical evidence
- Accelerate new tissue development projects with MTF

9

*Biologics Products*

The following table and discussion identify the principal Biologics products by trade name and describe their primary applications:

| Product | Primary Application |
|---|---|
| Trinity ELITE | A fully moldable allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure |
| Trinity Evolution | An allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure |
| AlloQuent Structural Allografts | Interbody devices made of cortical bone (or cortical-cancellous grafts) that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc during a spinal fusion procedure |
| Collage Synthetic Osteoconductive Scaffold | A synthetic bone void filler |
| VersaShield | A thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands |

The regenerative solutions offered as part of the Biologics reporting segment's portfolio include solutions for a variety of musculoskeletal defects used in spinal and extremity orthopedic procedures.

Regenerative Solutions

The premier biologics tissues we market include the Trinity ELITE and Trinity Evolution tissue forms, which are cortical cancellous allografts that contain viable cells and are used during surgery in the treatment of musculoskeletal defects for bone reconstruction and repair. These allografts are intended to offer a viable alternative to an autograft procedure as harvesting autograft has been shown to add risk of an additional surgical procedure and related patient discomfort in conjunction with a repair surgery.

To provide structural support and facilitate bone growth in spine fusion procedures, we offer a full line of AlloQuent allograft structural spacers derived from human cadaveric bone. These spacers are used to restore the height lost between vertebral bodies when discs are removed in fusion procedures and to facilitate spine fusion.

We offer the Collage product as an osteoconductive scaffold and a bone graft substitute product. The product is a combination synthetic bone graft substitute comprised of beta tri-calcium phosphate and type 1 bovine collagen.

We also market the VersaShield tissue form, a thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands. Amniotic tissue forms derived from donated human placenta are used in a wide variety of applications and are valued for their healing properties, scar reduction and anti-adhesion characteristics. The VersaShield tissue is derived from the human placental layers amnion and chorion, thin elastic membranes that allow the tissue to conform to the surface of the surgical site.

We receive marketing fees through our collaboration with MTF for the Trinity Evolution, Trinity ELITE, and VersaShield tissues. MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are submitted by customers via purchase orders. We have exclusive worldwide rights to market the Trinity Evolution and Trinity ELITE tissue forms. We market the VersaShield tissue under a private label brand via a non-exclusive marketing agreement for the tissue form.

To date, our Biologics products are offered primarily in the U.S. market due in part to restrictions on providing U.S. human donor tissue in other countries.

**Orthofix Extremities**

The Orthofix Extremities reporting segment offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This reporting segment specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. We distribute theseproducts through a global network of distributors and sales representatives to sell our orthopedic products to hospitals and healthcare providers.

Orthofix Extremities Strategy

Our strategy for the Orthofix Extremities reporting segment is to continue to provide highly valued external and internal temporary to definitive fixation devices used in fracture repair, deformity correction and bone reconstruction. Our key strategies in this segment are:

- Geographic market & product focus on:
  - Pediatrics & deformity correction worldwide
  - Foot & ankle in the U.S.
  - Trauma in selected geographies
- Promote the advantages of our JuniOrtho pediatric portfolio and support tools
- Leverage the market acceptance of TL-Hex
- Continue the strong pace of new product launches
- Acquire or license products, technologies and companies to support these market opportunities.

Orthofix Extremities Products

The following table and discussion identify the principal Orthofix Extremities products by trade name and describe their primary applications:

| Product | Primary Application |
|---|---|
| External Fixator | External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus, XCaliber and Gotfried P.C.C.P |
| Eight-Plate + Guided Growth System | The 2nd generation plate for treatment for bowed legs or knock knees of children |
| LRS Advanced Limb Reconstruction System | External fixation for limb lengthening and corrections of deformity |
| TrueLok | Ring fixation system for trauma, limb lengthening, and deformity correction |
| TL-HEX TrueLok Hexapod System ("TL-HEX") | Hexapod external fixation system for trauma and deformity correction with associated software |
| HEX RAY | An innovative software to manage pre-operation and post-operation planning in connection with the TL-HEX system |
| Galaxy Fixation System | |

| | |
|---|---|
| | External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps |
| VeroNail Trochanteric Nailing System | Trochanteric titanium nailing system for hip fractures |
| Centronail Titanium Nailing System | Complete range of intramedullary nails including the Humeral Nail |
| Ankle Hind Foot Nailing System (“AHN”) | An extension of the Centronail range of intramedullary nails |

| Product | Primary Application |
|---|---|
| Chimaera Hip Fracture System | A strong, versatile hip nail that allows fixation to be adapted to the type of fracture being treated |
| Agile Nail | A small rigid intramedullary nail to treat adolescent patients |
| MJ FLEX | An innovative elastic nail with a unique design to be used in pediatric patients |
| OSCAR | Ultrasonic bone cement removal |
| Ankle Hindfoot Nail (“AHN”) | A differentiated solution for hindfoot fusions |
| Contours Lapidus Plating System (“LPS”) | A plate design contoured specifically for a tarsometatarsal (“TMT”) fusion |
| Contours VPS Volar Plating System III | The 3rd generation of plates to treat distal radius fractures |

We provide internal and external fixation solutions for extremity repair and deformity correction, both for adults and children. Our fracture repair products consist of fixation devices designed to stabilize a broken bone until it can heal. With these devices, we can treat simple and complex fracture patterns along with achieving deformity corrections.

External Fixation

External fixation devices are used to stabilize fractures and offer an ideal treatment for complex fractures, fractures near the joints and in patients with known risk factors or co-morbidities. The treatment method entails the use of bone screws and/or wires which are inserted percutaneously into the bone and stabilized with an external device. The treatment is minimally invasive and allows external manipulation of the bone to obtain and maintain final bone alignment (reduction). The bone is fixed in this way until healing. External fixation devices may also be used temporarily in complex trauma cases to stabilize the fracture prior to treating it definitively. In these situations, the device offers rapid fracture stabilization, which is important in life saving as well as limb salvage procedures.

The Galaxy Fixation System is a modular external fixation system indicated for fracture treatment in the upper and lower limbs. The system incorporates a streamlined combination of clamps, with both pin-to-bar and bar-to-bar coupling capabilities, offering a complete range of applications, including specific anatomic units for the elbow, shoulder and wrist. It is designed both for temporary as well as definitive fracture fixation. It is also available in sterile kits for convenience and ease of use.

The XCaliber external fixator, made of lightweight radiolucent material, offers improved X-ray visualization of the fracture and alignment. It is available in three configurations for the treatment of long bone fractures, fractures near joints, and ankle fractures. XCaliber fixators are supplied pre-assembled, ready to use, in sterile kits to decrease time in the operating room.

The LRS Advanced Limb Reconstruction System uses callus distraction to lengthen bone in a variety of procedures, including monofocal lengthening and corrections of deformity. Its multifocal procedures include bone transport, simultaneous compression and distraction at different sites, bifocal lengthening, and correction of deformities with shortening.

The TrueLok Ring Fixation System is a surgeon-designed, lightweight external fixation system for limb lengthening and deformity correction. In essence, a ring fixation construct consists of circular rings and semi-circular external supports centered on the patient's limb and secured to the bone by crossed, tensioned wires and half pins. The rings are connected externally to provide stable bone fixation. The main external connecting elements are threaded rods, linear distractors, or hinges and angular distractors, which allow the surgeon to adjust the relative position of rings to each other. The ring positions are manipulated either acutely or gradually in precise increments to perform the correction of the deformity, limb lengthening, or bone segment transportation as required by the surgeon. Created with pre-assembled function blocks, the TrueLok products are a simple, stable, versatile ring fixation system.

Building on the TrueLok brand, the TL-HEX TrueLok Hexapod System was released in 2012 in international markets and in 2015 in the U.S. TL-HEX is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. The system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings' position is adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) can be utilized with the TL-HEX system; therefore, external supports from both systems can be connected to each other when building fixation blocks.

The new addition of HEX-Ray software to the TL-HEX platform allows a unique and realistic representation of the case using real x-rays and providing more accurate and user-friendly management of the surgery. The software is intended to help the surgeon save time by avoiding undesired corrections and mistakes related to software management.

Linked to the TL and TL-HEX line, we have also developed a patient app to support the patient in the TL-HEX fixator daily management. The patient is an active part in the healing process and the app is designed to improve the communication and connection with the hospital staff by saving time, optimizing the number of visits to the clinic, and supporting the patient with motivational messages and an online tutorial to sort out the most common issues. Also related to the TL and TL-HEX line, but specifically developed for younger patients, we created the Edugame, an online app to help patient learn by playing a virtual game. It has been developed with psychologist involvement in order to deliver useful information in an effective way.

Our proprietary XCaliber bone screws are designed to be compatible with our external fixators and reduce inventory for our customers. Some of these screws are covered with hydroxyapatite, a mineral component of bone that reduces superficial inflammation of soft tissue and improves bone grip. Other screws in this proprietary line do not include the hydroxyapatite coating, but offer different advantages such as patented thread designs for better adherence in hard or poor quality bone. Adding to the XCaliber bone screw product line are our cylindrical screws, which are geared towards the trauma applications of the Galaxy Fixation System. We believe we have a full line of bone screws to meet the demands of the market.

In 2017, we introduced JuniOrtho, a new brand identity for extremity fixation pediatric products. JuniOrtho is a range of products and resources dedicated to pediatrics and young adults with bone fractures and deformities that brings together our expertise and products in the pediatric space.

Internal Fixation

Internal fixation devices come in various sizes, depending on the bone that requires treatment, and consist of either long rods, commonly referred to as nails, or plates that are attached with the use of screws. A nail is inserted into the medullary canal of a fractured long bone of the human arm or leg (e.g., humerus, femur or tibia). Alternatively, a plate is attached by screws to an area such as a broken wrist, hip or foot. Examples of our internal fixation devices include:

- The Chimaera Hip Nailing System, which is indicated for the treatment of hip fractures. The Chimaera hip nail is designed to offer improvements over currently available nails by taking advantage of decades of knowledge in hip nailing. The result is a strong, versatile nail that allows fixation to be adapted to the type of fracture being treated. An all-in-one dedicated instrument tray contains a color-coded instrument set designed for increased precision during the surgical steps as well as intuitive instrument selection.
- The VeroNail Trochanteric Nailing System, which is indicated for the treatment of hip fractures. The nail design is minimally-invasive to reduce surgical trauma and allow patients to begin walking again shortly after the operation. It

uses a dual screw configuration that we believe provides more stability than previous single screw designs.

- The Centronail Titanium Nailing System, which comprises a range of titanium nails to stabilize fractures in the femur, tibia and humerus. The system offers improved mechanical distal targeting and minimal instrumentation to optimize inventory.
- The Ankle Hindfoot Nail, which is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails.
- The Agile Nail, which is designed to treat femoral fractures in patients where a small rigid nail is needed. Its unique design requires less inventory and is the smallest titanium nail currently available in the market. This provides further benefits such as reduced invasiveness and lightness.

- The MJ Flex, which is an elastic nail system that innovates a technique considered to be the gold standard in the treatment of pediatric fractures. The unique shape of the nail offers improved strength, better visibility, more rigidity, and potentially a reduced usage of x-rays. The system is available in different sizes, both in titanium and stainless steel.

In addition to treating bone fractures, we also design, manufacture and distribute devices intended to treat congenital bone conditions, such as angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as conditions resulting from a previous trauma. An example of a product offered in this area is the Eight-Plate Guided Growth System.

Product Development

Our primary research and development facilities are located in Verona, Italy and Lewisville, Texas. We work with leading hospital research institutions, as well as with MTF, physicians and other consultants, on the long-term scientific planning and evolution of our products and therapies. Several of the products that we market have been developed through these collaborations. In addition, we periodically receive suggestions for new products and product enhancements from the scientific and medical community, some of which result in us entering into assignment or license agreements with physicians and third parties.

In 2018, 2017 and 2016 we incurred $33.2 million, $29.7 million and $28.8 million, respectively, of research and development expense.

Patents, Trade Secrets, Assignments and Licenses

We rely on a combination of patents, trade secrets, assignment and license agreements, and non-disclosure agreements to protect our proprietary intellectual property. We own numerous U.S. and foreign patents, have numerous pending patent applications and have license rights under patents held by third parties. Our primary products are patented in the major markets in which they are sold. No assurance can be given that pending patent applications will result in issued patents, that patents issued or assigned to or licensed by us will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with any competitive advantage or protection. Third parties might also obtain patents that would require assignments to or licensing by us to conduct our business. We rely on confidentiality and non-disclosure agreements with key employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology.

We obtain assignments or licenses of varying durations for certain of our products from third parties. We typically acquire rights under such assignments or licenses in exchange for lump-sum payments or arrangements under which we pay a percentage of sales to the licensor. However, while assignments or licenses to us generally are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years to the life of product patents or the economic life of the product. These agreements generally provide for royalty payments and termination rights in the event of a material breach.

Compliance and Ethics Program

It is a fundamental policy of our Company to conduct business in accordance with the highest ethical and legal standards. We have a comprehensive compliance and ethics program, which is overseen by our Chief Ethics and Compliance Officer who reports directly to our Chief Executive Officer and the Compliance Committee of the Board of Directors. The program is intended to promote legal compliance and ethical business practices throughout our domestic and international businesses. It is designed to prevent and detect violations of applicable federal, state and local laws in accordance with the standards set forth in guidance issued by the U.S. Department of Justice (“Evaluation

of Corporate Compliance Programs" (February 2017)), the Office of Inspector General (HCCA-OIG "Measuring Compliance Program Effectiveness: A Resource Guide" (March 2017)) and the U.S. Sentencing Commission ("Effective Compliance and Ethics Programs (November 2014)). Key elements of the program include:

- Organizational oversight by senior-level personnel responsible for the compliance function within our Company;
- Written standards and procedures, including a Corporate Code of Conduct;
- Methods for communicating compliance concerns, including anonymous reporting mechanisms;
- Investigation and remediation measures to ensure prompt response to reported matters and timely corrective action;
- Compliance education and training for employees and contracted business associates;
- Auditing and monitoring controls to promote compliance with applicable laws and assess program effectiveness;

- Disciplinary guidelines to enforce compliance and address violations;
- Due diligence reviews of high risk intermediaries and exclusion lists screening of employees and contracted business associates; and
- Risk assessments to identify areas of compliance risk.

Government Regulation

Classification and Approval of Products by the FDA and other Regulatory Authorities

Our research, development and clinical programs, and our manufacturing and marketing operations, are subject to extensive regulation in the U.S. and other countries. Most notably, all of our products sold in the U.S. are subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act as implemented and enforced by the FDA. The regulations that cover our products and facilities vary widely from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

Unless an exemption applies, each medical device we commercially distribute in the U.S. is covered by premarket notification ("510(k)") clearance, letter to file, approval of a premarket approval application ("PMA"), or some other approval from the FDA. The FDA classifies medical devices into one of three classes, which generally determine the type of FDA approval required. Devices deemed to pose low risk are placed in class I, while devices that are considered to pose moderate risk are placed in class II, and devices deemed to pose the greatest risks requiring more regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, or devices deemed not substantially equivalent to a device that previously received 510(k) clearance (as described below), are placed in class III. Our Spinal Implants and Orthofix Extremities products are, for the most part, class II devices and the instruments used in conjunction with these products are generally class I. Our Bone Growth Therapies products and the M6-C artificial cervical disc are classified as class III by the FDA, and have been approved for commercial distribution in the U.S. through the PMA process.

The medical devices we develop, manufacture, distribute and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no assurance such approvals will be granted on a timely basis, if at all. While we believe we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance.

To market our devices within the member states of the European Union, we are required to comply with the European Medical Device Directives. Under the European Medical Device Directives, all medical devices must bear the CE mark. To obtain authorization to affix the CE mark to our products, a recognized European Notified Body must assess our quality systems and the product's conformity to the requirements of the European Medical Device Directives. We are subject to an annual inspection by a Notified Body for compliance with these requirements.

Our Biologics reporting segment markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE, our allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. These allografts are regulated under the FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device, biologic or a drug. The Biologics reporting segment also distributes certain surgical implant products known as "allograft" products that are derived from human tissues and which are used for bone reconstruction or repair and are surgically implanted into the human body. These tissues are regulated by the FDA as minimally-manipulated tissue and covered by FDA's "Good

Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance our suppliers of the Trinity Evolution, Trinity ELITE and allograft products will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bones are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a further description of some of these risks, see Item 1A of this Annual Report under the heading "Risk Factors."

*Certain Other Product and Manufacturing Regulations*

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and governmental prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical Device Adverse Event Reporting regulations, which require that manufacturers report to the FDA and other foreign governmental agencies if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA and European Notified Bodies to determine our compliance with the FDA's QSR and other international regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. In addition to FDA inspections, all manufacturing facilities of the Company are subject to annual Notified Body inspections.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices. Our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. For a description of some of these risks, see Item 1A of this Annual Report under the heading "Risk Factors."

Accreditation Requirements

In addition, our subsidiary Orthofix Inc. has been accredited by the Accreditation Commission for Health Care, Inc. ("ACHC") for medical supply provider services with respect to durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). ACHC, a private, not-for-profit corporation, which is certified to ISO 9001:2000 standards, was developed by home care and community-based providers to help companies improve business operations and quality of patient care. Although accreditation is generally a voluntary activity where healthcare organizations submit to peer review their internal policies, processes and patient care delivery against national standards, the Centers for Medicare and Medicaid Services ("CMS") required DMEPOS suppliers to become accredited. We believe that by attaining accreditation, Orthofix Inc. has demonstrated its commitment to maintain a higher level of competency and strive for excellence in its products, services, and customer satisfaction.

Third-Party Payor Requirements

Our products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid, and Tricare or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. Also, non-government third-party payors are increasingly challenging the medical necessity and prices paid for our products and services. The Medicare program is expected to continue to implement a new payment mechanism for certain DMEPOS items via the implementation of its competitive bidding program. Bone growth therapy devices are currently exempt from this competitive bidding process.

*Laws Regulating Healthcare Fraud and Abuse; State Healthcare Laws*

Our sales and marketing practices are also subject to a number of U.S. laws regulating healthcare fraud and abuse such as the federal Anti-Kickback Statute and the federal Physician Self-Referral Law (known as the "Stark Law"), the Civil False Claims Act and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as well as numerous state laws regulating healthcare and insurance. These laws are enforced by the Office of Inspector General within the U.S. Department of Health and Human Services, the U.S. Department of Justice, and other federal, state and local agencies. Among other things, these laws and others generally: (1) prohibit the provision of anything of value in exchange for the referral of patients for, or the purchase, order, or recommendation of, any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require that claims for payment submitted to federal healthcare programs be truthful; (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (4) require the maintenance of certain government licenses and permits.

Laws Protecting the Confidentiality of Health Information

U.S. federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information such as medical records, and restrict the use and disclosure of that protected information. At the federal level, the Department of Health and Human Services promulgates health information privacy and security rules under HIPAA. These rules protect health information by regulating its use and disclosure, including for research and other purposes. Failure of a HIPAA "covered entity" to comply with HIPAA regarding such "protected health information" could constitute a violation of federal law, subject to civil and criminal penalties. Covered entities include healthcare providers (including certain of those that sell devices or equipment) that engage in particular electronic transactions, including, as we do, the transmission of claims to health plans. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose includes protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

In Europe, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data.

Physician Payments Sunshine Provision of the Affordable Care Act

The Physician Payments Sunshine Provision of the Affordable Care Act (Section 6002) (the "Sunshine Act"), which was enacted in 2010 and became subject to final CMS rules in 2013, requires public disclosure to the United States government of payments to physicians and teaching hospitals, including in-kind transfers of value such as gifts or meals. The Act also provides penalties for non-compliance. The Act requires that we file an annual report on March 31st of a calendar year for the transfers of value incurred for the prior calendar year.

In October 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act") was signed into law. The SUPPORT Act expands the reporting obligation under the Sunshine Act to include payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. These expanded reporting obligations are effective for payments reported in 2022, with payment tracking beginning in 2021. Non-compliance with the Sunshine Act or SUPPORT Act is subject to civil monetary penalties.

In addition to the Sunshine Act, as expanded by the SUPPORT Act, we seek to comply with other international and individual state transparency laws, like Massachusetts and Vermont.

Sales, Marketing and Distribution

General Trends

We believe that demographic trends, principally in the form of a better informed, more active and aging population in the major healthcare markets of the U.S., Western Europe and Japan, together with opportunities in emerging markets such as the Asia-Pacific Region and Latin America, as well as our focus on innovative products, will continue to have a positive effect on the demand for our products.

*Reporting Segments*

Our revenues are generated from the sales of products in our four reporting segments: Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities. See the chart below for the distribution of sales between each of our reporting segments for each of the years ended December 31, 2018, 2017, and 2016.

Sales Network

We have a broad sales network comprised of direct sales representatives and distributors. This established sales network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in over 70 countries.

In our largest market, the U.S., our sales network is generally comprised of four sales forces, each addressing one of our reporting segments, however some independent distributors sell products for more than one of our segments. A hybrid distribution network of direct sales representatives and independent distributors sells products in our Bone Growth Therapies reporting segment, while primarily independent distributors sell products in our Spinal Implants, Biologics, and Orthofix Extremities reporting segments.

Outside the U.S., we employ direct sales representatives and contract with independent distributors. In order to provide support to our independent sales network, we have sales and marketing specialists who regularly visit independent distributors to provide training and product support.

Marketing and Product Education

We market and sell our products principally to physicians, hospitals, ambulatory surgery centers, integrated health delivery systems and other purchasing organizations.

We support our sales force through specialized training workshops in which physicians and sales specialists participate. We also produce marketing and training materials, including materials outlining surgical procedures, for our customers, sales force and distributors in a variety of languages using printed, video and multimedia formats. We require all of our sales force, direct and independent, to undergo extensive product, policy, and compliance training to ensure adherence to our standards, policies, and applicable law.

To provide additional advanced training for physicians, consistent with the AdvaMed Code of Ethics (“AdvaMed Code”) and the MedTech Europe Code of Ethical Business Practice (“MedTech Code”), we organize regular multilingual teaching seminars in multiple locations. Those places include our facility in Verona, Italy, various locations in Latin America and in Lewisville, Texas. In recent years, thousands of surgeons from around the world attended these product education seminars, which have included a variety of lectures from specialists, as well as demonstrations and hands-on workshops.

**Competition**

Our Bone Growth Therapies reporting unit competes principally with similar products marketed by Zimmer Biomet, Inc.; DJO Global; and Bioventus. The Biologics HCT/P and Spinal Implants products we market compete with products marketed by Medtronic, Inc.; DePuy Synthes, a division of Johnson and Johnson; Stryker Corp.; Zimmer Biomet, Inc.; NuVasive, Inc.; Globus Medical Inc.; and various smaller public and private companies. For Orthofix Extremities devices, our principal competitors include DePuy Synthes; Zimmer Biomet, Inc.; Stryker Corp.; Smith & Nephew plc; and Wright Medical Group N.V.

We believe that we enhance our competitive position by focusing on product features such as ease of use, versatility, cost and patient acceptability, together with value-added services, such as the STIM on Track mobile app and our JuniOrtho educational products and services. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, value-added service, and training are the most prevalent methods of competition in the markets for our products, and we believe we compete effectively.

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation, orthopedic, and spinal implant products, and subcontract the manufacture of a substantial portion of the component parts and instruments. We design and develop our AlloQuent Allograft HCT/Ps and subcontract its manufacturing. Through subcontracting a portion of our manufacturing, we attempt to maintain operating flexibility in meeting demand while focusing our resources on product development, education and marketing as well as quality assurance standards. Although certain of our key raw materials are obtained from a single source, we believe alternate sources for these materials are available. Further, we believe an adequate inventory supply is maintained to avoid product flow interruptions. Historically, we have not experienced difficulty in obtaining the materials necessary to meet our production schedules.

The Trinity Evolution and Trinity ELITE HCT/Ps, for which we have exclusive marketing rights, are allograft tissue forms that are supplied to customers by MTF in accordance with orders received directly from us. MTF sources, processes and packages the tissue forms and is the sole supplier of the Trinity Evolution and Trinity ELITE HCT/Ps to our customers.

Our products are currently manufactured and assembled in the U.S. and Italy. We believe our plants comply in all material respects with the requirements of the FDA and all relevant regulatory authorities outside the U.S. For a description of the laws to which we are subject, see Item 1, “Business”, under the subheadings “Corporate Compliance and Ethics Program” and “Government Regulation.” We actively monitor each of our subcontractors in order to maintain manufacturing and quality standards and product specification conformity.

Employees

At December 31, 2018, we had 954 employees worldwide. Of these, 686 were employed in the U.S. and 268 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 187 at December 31, 2018, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. We are not a party to any other collective bargaining agreement. We believe we have good relations with our employees.

**Item 1A.** Risk Factors

In addition to the other information contained in this Annual Report and the exhibits hereto, you should carefully consider the risks described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Annual Report

also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Annual Report.

**Risks Related to our Legal and Regulatory Environment**

If we fail to maintain an effective system of internal controls or discover material weaknesses in our internal control over financial reporting, we may not be able to report our financial results accurately or detect fraud, which could harm our business and the trading price of our Common Stock.

Effective internal controls are necessary for us to produce reliable financial reports and are important in our effort to prevent financial fraud. We are required to periodically evaluate the effectiveness of the design and operation of our internal controls. As has occurred in several years prior, these evaluations may result in the conclusion that enhancements, modifications or changes to our internal controls are necessary or desirable. While management evaluates the effectiveness of our internal controls on a regular basis, these controls may not always be effective. There are inherent limitations on the effectiveness of internal controls, including collusion, management override, and failure of human judgment. Because of this, control procedures are designed to reduce rather than eliminate business risks. If we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, which could harm our financial condition and operating results, and could result in a loss of investor confidence and a decline in our stock price.

We have previously settled violations of the Foreign Corrupt Practices Act and any future violations could further subject us to adverse consequences.

In 2013, we self-reported to the U.S. Department of Justice (the “DOJ”) and the SEC an internal investigation of improper payments by our Brazilian subsidiary, Orthofix do Brasil Ltda., regarding non-compliance by such subsidiary with the Foreign Corrupt Practices Act (the “FCPA”). This followed a prior matter that we self-reported to the DOJ and SEC in 2011, and settled in 2012, involving FCPA-related non-compliance by our then Mexican subsidiary, Promeca S.A. de C.V. In January 2017 we consented to a cease-and-desist order with the SEC to settle the Brazil-related violations, pursuant to which we agreed to pay approximately $6.1 million in disgorgement and penalties, and agreed to retain an independent compliance consultant for one year to review and test our FCPA compliance program. Our engagement of the independent compliance consultant concluded on March 16, 2018.

The FCPA and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on U.S. publicly traded entities and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws.

In connection with our self-reported FCPA violations, we instituted extensive remediation measures, including terminating employees, as well as relationships with third-party representatives and distributors, conducting a global review of our anti-corruption and anti-bribery program, implementing regular audits of our third-party distributors and sales agents and developing and implementing new global accounting policies to provide further structure and guidance to foreign subsidiaries, establishing an internal audit function, improving the quality of personnel in our Compliance department, and implementing enhanced anti-corruption compliance training for employees and certain third parties. However, notwithstanding these efforts to make FCPA-related compliance a priority, our compliance policies and procedures may not always protect us from reckless or criminal acts committed by our employees, distributors or agents.

Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities, disgorgement and other remedial measures, disruptions of our operations, and significant management distraction. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

We are subject to federal and state healthcare fraud, abuse and anti-self-referral laws, and could face substantial penalties if we are determined not to have fully complied with such laws.

Healthcare fraud and abuse regulations by federal and state governments impact our business. Healthcare fraud and abuse laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program (such as the Medicare or Medicaid programs);
- the federal Stark law, which prohibits physician self-referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services if the physician or an immediate family member has a financial relationship with that entity;
- federal false claims laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and
- state and non-U.S. laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental or non-U.S. governmental third-party payors, including commercial insurers.

Due to the breadth of some of these laws, there can be no assurance that we will not be found to be in violation of any such laws, and as a result we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations or the exclusion from participation in federal, non-U.S. or state healthcare programs. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Reimbursement policies of third parties, cost containment measures and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products.

Our products are sold either directly by us or by independent sales representatives to customers or to our independent distributors and purchased by hospitals, healthcare providers, and patients. These products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid and Tricare, or private insurance plans and healthcare networks. Major third-party payors for medical services in the U.S. and internationally continue to work to contain health care costs and are increasingly challenging the policies and the prices charged for medical products and services. Any medical policy developments that eliminate, reduce or materially modify coverage of our reimbursement rates for our products could have an impact on our ability to sell our products. In addition, third-party payors may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. These policies and criteria may be revised from time-to-time.

Limits put on reimbursement could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. In addition, should governmental authorities continue to enact legislation or adopt regulations that affect third-party coverage and reimbursement, access to our products and coverage by private or public insurers may be reduced with a consequential material adverse effect on our sales and profitability.

CMS, in its ongoing implementation of the Medicare program, periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that this information could have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many countries, such as the U.K., Germany, France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, CMS has continued efforts to implement a competitive bidding program for selected durable medical equipment, prosthetic, orthotic supplies ("DMEPOS") items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Bone growth stimulation products are currently exempt from this competitive bidding process. We cannot predict which products from any of our businesses may ultimately be affected or whether or when the competitive bidding process may be extended to our businesses. There can be no assurance that the implementation of the competitive bidding program will not have an adverse impact on the sales of some of our products.

*We and certain of our suppliers may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.*

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacturing, labeling, marketing and sale of medical devices. Likewise, our use and disclosure of certain categories of health information may be subject to federal and state laws, implemented and enforced by governmental authorities that protect health information privacy and security. For a description of these regulations, see Item 1, "Business," under the subheading "Government Regulation."

The approval or clearance by governmental authorities, including the FDA in the U.S., is generally required before any medical devices may be marketed in the U.S. or other countries. We cannot predict whether, in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition, results of operations or cash flows. The process of obtaining FDA clearance and approvals to develop and market a medical device can be costly, time-consuming and subject to the risk that such clearances or approvals will not be granted on a timely basis, if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification, or to reclassify an HCT/P, either of which could materially adversely impact our ability to market or sell our devices. For example, the FDA included Class III bone growth stimulator products in its 2015 strategic priority work plan, as part of a list of 21 product categories it would review for possible down classification. Shortly after the issuance of the work plan, we and other manufacturers of bone growth stimulator products submitted a public comment letter opposing the possible down classification. The FDA did not respond to the comment letter and has not taken any action with respect to the bone growth stimulator product category since publication of the 2015 work plan. If a down classification were to occur and new entrants to the market were able to create technologies with comparable efficacy to our devices, our Bone Growth Therapies products could face additional competition, which could negatively affect our future sales.

In addition, we may be subject to compliance actions, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses, or if the FDA challenges one or more of our determinations that a product modification did not require new approval or clearance by the FDA. Device manufacturers are permitted to promote products solely for the uses and indications set forth in the approved product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses, including actions alleging that federal health care program reimbursement of products promoted for "off-label" uses are false and fraudulent claims to the government. The failure to comply with "off-label" promotion restrictions can result in significant administrative obligations and costs, and potential penalties from, and/or agreements with, the federal government.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of the foregoing actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission ("EC") has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a "Notified Body" in order to be able to sell products within the member states of the European Union. This Certification allows manufacturers to stamp the products of certified plants with a "CE" mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the European Union. We have received certification for all currently existing manufacturing facilities.

*The impact of the Affordable Care Act and other United States healthcare reform legislation on us remains uncertain.*

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the ACA:

- requires certain medical device manufacturers to pay an excise tax equal to 2.3% of the price for which such manufacturer sells its medical devices; this excise tax was previously suspended until December 31, 2017. On January 22, 2018, the President signed the Extension of Continuing Appropriations Act, 2018, which extended the moratorium on the tax until December 31, 2019.
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

Certain legislative changes to and regulatory changes under the ACA have occurred in the 115th United States Congress. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to the ACA and changes resulting from current litigation challenging certain aspects of the ACA remains possible. Any such future changes, depending on their nature, could have an adverse effect on our ability to maintain or increase sales of any of our products and achieve profitability.

We are subject to differing customs and import/export rules in several jurisdictions in which we operate.

We import and export our products to and from a number of different countries around the world. These product movements involve subsidiaries and third parties operating in jurisdictions with different customs and import/export rules and regulations. Customs authorities in such jurisdictions may challenge our treatment of customs and import/export rules relating to product shipments under aspects of their respective customs laws and treaties. If we are unsuccessful in defending our treatment of customs and import/export classifications, we may be subject to additional customs duties, fines or penalties that could adversely affect our profitability.

Risks Related to our Business and Industry

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a group purchasing organization or similar entity excludes us from being a supplier.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators and third-party payors to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including medical device companies and hospitals, each with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This has resulted and may continue to result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations (“GPOs”), independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions and as larger manufacturers use their broad offerings to secure exclusive arrangements. If a GPO were to exclude us from their supplier list, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on

the prices of our products.

The industry in which we operate is highly competitive. New developments by others could make our products or technologies non-competitive or obsolete.

The medical devices industry is highly competitive. We compete with a large number of companies, many of which have significantly greater financial, manufacturing, marketing, distribution and technical resources than we do. Many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. For more information regarding our competitors, see Item 1, “Business,” under the subheading “Competition.”

In addition, the orthopedic medical device industry in which we compete is undergoing, and is characterized by, rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products developed by other companies are regularly introduced into the market, which may render our products or technologies non-competitive or obsolete.

Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties.

Our ability to market our Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, physicians, other healthcare providers and third-party payors) as well as patients. Unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to maintain hospital approvals or achieve acceptance by prescribing physicians, managed care providers and other retailers, customers and patients.

Our allograft and mesenchymal stem cell allografts could expose us to certain risks that could disrupt our business.

Our Biologics business markets allograft tissues that are derived from human cadaveric donors, and our ability to market the tissues depends on our supplier continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards by the supplier in its processing methodology. The supply of such donors is inherently unpredictable and can fluctuate over time. The allograft tissues are regulated under the FDA's HCT/P regulatory paradigm and not as a medical device or as a biologic or drug. There can be no assurance that the FDA will not at some future date re-classify the allograft tissues, and the reclassification of this product from a human tissue to a medical device could have adverse consequences for us or for the supplier of this product and make it more difficult or expensive for us to conduct this business by requiring premarket clearance or approval as well as compliance with additional post-market regulatory requirements.

We may not be able to successfully introduce new products to the market, and market opportunities that we expect to develop for our products may not be as large as we expect.

During 2018, we continued to make improvements in revenues related to several new products we introduced to the market over the past several years, including the TL-HEX TrueLok Hexapod System, Galaxy Fixation System, Chimaera Hip Fracture System, Ankle Hind Foot Nailing System, Firebird NXG Spinal Fixation System, FORZA XP Spacer System, SKYHAWK Lateral Interbody Fusion System & Lateral Plate System, CENTURION POCT System, PILLAR SA PTC PEEK Spacer System, JANUS Midline Fixation Screw, and the Cetra Anterior Cervical Plate, among others. In 2019, we will be launching the M6-C artificial certivical disc in the U.S. market. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians) and obtain regulatory approvals, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

Growing our business requires that we properly educate and train physicians regarding the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.

Acceptance of our products depends in part on our ability to (i) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies, and (ii) train physicians in the proper use and implementation of our products. We

support our sales force and distributors through specialized training workshops in which surgeons and sales specialists participate. We also produce marketing materials, including materials outlining surgical procedures, for our sales force and distributors in a variety of languages using printed, video and multimedia formats. To provide additional advanced training for surgeons, consistent with the AdvaMed Code and the MedTech Code, we organize regular multilingual teaching seminars in multiple locations. However, we may not be successful in our efforts to educate the medical community and properly train physicians. If physicians are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products.

*We may be adversely affected by any disruption in our information technology systems, which could adversely affect our cash flows, operating results and financial condition.*

Our operations are dependent upon our information technology systems, which encompass all of our major business functions. We rely upon such information technology systems to manage and replenish inventory, to fill and ship customer orders on a timely basis, to coordinate our sales activities across all of our products and services and to coordinate our administrative activities. A substantial disruption in our information technology systems for any prolonged time period (arising from, for example, system capacity limits from unexpected increases in our volume of business, outages or delays in our service) could result in delays in receiving inventory and supplies or filling customer orders and adversely affect our customer service and relationships. Our systems might be damaged or interrupted by natural or man-made events or by computer viruses, physical or electronic break-ins and similar disruptions affecting the global Internet. There can be no assurance that such delays, problems, or costs will not have a material adverse effect on our cash flows, operating results and financial condition.

As our operations grow in both size and scope, we will continuously need to improve and upgrade our systems and infrastructure while maintaining the reliability and integrity of our systems and infrastructure. An expansion of our systems and infrastructure may require us to commit substantial financial, operational and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. In particular, we recently upgraded our financial reporting system and other information technology systems as part of our infrastructure initiative, Project Bluecore. These and any other upgrades to our systems and information technology, or new technology, now and in the future, require that our management and resources be diverted from our core business to assist in compliance with those requirements. There can be no assurance that the time and resources our management will need to devote to these upgrades, service outages or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology will not have a material adverse effect on our cash flows, operating results and financial condition.

A significant portion of our operations run on a single Enterprise Resource Planning (“ERP”) platform. To manage our international operations efficiently and effectively, we rely heavily on our ERP system, internal electronic information and communications systems and on systems or support services from third parties. Any of these systems are subject to electrical or telecommunications outages, computer hacking or other general system failure. It is also possible that future acquisitions will operate on different ERP systems and that we could face difficulties in integrating operational and accounting functions of new acquisitions. Difficulties in upgrading or expanding our ERP system or system-wide or local failures that affect our information processing could adversely affect our cash flows, operating results and financial condition.

We may be adversely affected by a failure or compromise from a cyberattack or data breach, which could have an adverse effect on our business

We rely on information technology (IT) systems to perform our business operations, including processing, transmitting and storing electronic information, and interacting with customers, suppliers, healthcare payors, and other third parties. Like other medical device companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect financial or personal information related to patients and customers, and changing customer patterns.

For example, third parties may attempt to hack into our products to obtain data relating to patients or disrupt performance of our products or to access our proprietary information. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In the U.S., Federal and State privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs of compliance with such rules are not material to our business. However, there is no guarantee that we will be able to comply with these regulations, or otherwise avoid the negative reputational and other affects that might ensue from a significant data breach or failure to comply with applicable data privacy regulations, each of which could have significant adverse effects on our business, financial condition or results of operations.

In recent years, companies around the world are seeing a surge in wire transfer “phishing” attacks that attempt to trick employees into wiring money from company bank accounts to criminals’ bank accounts. In some cases, companies have lost millions of dollars to such relatively simple attacks, and these funds often are not recovered. While we take efforts to train employees to be cognizant of these types of attacks and take appropriate precautions, the level of technological sophistication being used by attackers has increased in recent years, and a successful attack against us could lead to the loss of significant funds.

We are dependent on third-party manufacturers for many of our products.

We contract with third-party manufacturers to produce many of our products, like many other companies in the medical device industry. If we or any such manufacturer fail to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third-party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of the Trinity Evolution and Trinity ELITE allografts are derived from human cadaveric donors, and our ability to market the tissues depends on MTF continuing to have access to donated human cadaveric tissue, as well as, the maintenance of high standards by MTF in its processing methodology.

Termination of our existing relationships with our independent sales representatives or distributors could have an adverse effect on our business.

We sell our products in many countries through independent distributors. Generally, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories. The terms of these agreements vary in length, generally from one to ten years. Under the terms of our distribution agreements, each party has the right to terminate in the event of a material breach by the other party and we generally have the right to terminate if the distributor does not meet agreed sales targets or fails to make payments on time. Any termination of our existing relationships with independent sales representatives or distributors could have an adverse effect on our business unless and until commercially acceptable alternative distribution arrangements are put in place. In addition, we operate in areas of the world that have been or may be disproportionately affected by recessions and we bear risk that existing or future accounts receivable may be uncollected if these distributors or hospitals experience disruptions to their business that cause them to discontinue paying ongoing accounts payable or become insolvent.

We depend on our senior management team.

Our success depends upon the skill, experience and performance of members of our senior management team, who have been critical to the management of our operations and the implementation of our business strategy. We do not have key man insurance on our senior management team, and the loss of one or more key executive officers could have a material adverse effect on our operations and development.

In order to compete, we must attract, retain and motivate key employees, and our failure to do so could have an adverse effect on our results of operations.

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing, research, development, finance and support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified executives and key employees, we utilize stock-based incentive awards such as employee stock options, restricted stock and stock units. If the value of such stock awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate our

employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation.

Our business is subject to economic, political, regulatory and other risks associated with international sales and operations.

Because we sell our products in many different countries, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a substantial portion of our total net sales. In addition, a number of our manufacturing facilities and suppliers are located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in a specific country's or region's political or economic conditions;

- trade protection measures and import or export licensing requirements or other restrictive actions by foreign governments;
- consequences from changes in tax or customs laws;
- difficulty in staffing and managing widespread operations;
- differing labor regulations;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements; and
- violation by our independent agents of the FCPA or other anti-bribery or anti-corruption laws.

Risks Related to our Intellectual Property

We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that compete directly with, ours. Numerous patents covering our technologies have been issued to us, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U.S. Some patent applications in the U.S. are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by several months, we may not be the first to invent, or file patent applications on any of our discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to, or licensed by, us and may not provide adequate protection or competitive advantages for our products. Patents that are issued may be challenged, invalidated or circumvented by our competitors. Furthermore, our patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary expertise and continuing technological innovation that we protect, in part, by entering into confidentiality agreements with assignors, licensees, suppliers, employees and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. If patents are not issued with respect to our products arising from research, we may not be able to maintain the confidentiality of information relating to these products. In addition, if a patent relating to any of our products lapses or is invalidated, we may experience greater competition arising from new market entrants.

Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the medical device industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things:

- require us to incur substantial expense, even if we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and

- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the orthopedic medical devices industry have often been settled through assignments, licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. Furthermore, the required assignments or licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary assignments or licenses could prevent us from manufacturing and selling some products or increase our costs to market these products.

**Risks Related to Litigation and Product Liability Matters**

We may be subject to product and other liability claims that may not be covered by insurance and could require us to pay substantial sums. Moreover, fluctuations in insurance expense could adversely affect our profitability.

We are subject to an inherent risk of, and adverse publicity associated with, product liability and other liability claims, whether or not such claims are valid. We maintain product liability insurance coverage in amounts and scope that we believe are reasonable and adequate. There can be no assurance, however, that product liability or other claims will not exceed our insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful product liability claim that exceeds our insurance coverage limits could require us to pay substantial sums and could have a material adverse effect on our financial condition.

In addition to product liability insurance coverage, we hold a number of other insurance policies, including directors' and officers' liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted.

Risks Related to Potential Acquisitions and Divestitures

Our efforts to identify, pursue and implement new business opportunities (including acquisitions) may be unsuccessful and may have an adverse effect on our business.

Our growth depends, in large part, on our ability to identify, pursue and implement new business opportunities that expand our product offerings, capabilities and geographic presence, and we compete with other medical device companies for these opportunities. Our efforts to identify such opportunities focus primarily on potential acquisitions of new businesses, products or technologies, licensing arrangements, commercialization arrangements and other transactions with third parties. We may not be able to identify business opportunities that meet our strategic criteria or are acceptable to us or our shareholders. Even if we are able to identify acceptable business opportunities, we may not be able to pursue or implement such business opportunities (or, in the case of acquisitions or other transactions, complete such acquisitions or other transactions) in a timely manner or on a cost-effective basis (or at all), and we may not realize the expected benefits of such business opportunities. If we are not able to identify, pursue and implement new business opportunities, it will adversely affect our ability to grow our business.

In addition, pursuing and implementing new business opportunities (particularly acquisitions) may involve significant costs and entail risks, uncertainties and disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology or operating in a particular geographic region. We may be unable to integrate a new business, product or technology effectively, or we may incur significant charges related to an acquisition or other business opportunity (for example, amortization of acquired assets or asset impairment charges), which may adversely affect our business, financial condition and results of operations. Newly acquired technology or products may require additional development efforts prior to commercial sale, including clinical testing and approval by the FDA and applicable foreign regulatory authorities; such additional development efforts may involve significant expense and ultimately be unsuccessful. Any cross-border acquisitions or transactions may involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. To the extent we issue additional equity in connection with acquisitions, this may dilute our existing shareholders.

We may incur significant costs or retain liabilities associated with disposition activity.

We may from time to time sell, license, assign or otherwise dispose of or divest assets, the stock of subsidiaries or individual products, product lines or technologies, which we determine are no longer desirable for us to own, some of which may be material. Any such activity could result in our incurring costs and expenses from these efforts, some of which could be significant, as well as retaining liabilities related to the assets or properties disposed of even though, for instance, the income-generating assets have been disposed of. These costs and expenses may be incurred at any time and may have a material impact on our results of operations.

**Risks Related to Our Financial Results and Need for Financing**

Our quarterly operating results may fluctuate.

Our quarterly operating results have fluctuated significantly in the past. Our future quarterly operating results may fluctuate significantly, and we may experience losses depending on a number of factors, including the extent to which our products continue to gain or maintain market acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, the extent to which we are subject to government regulation or enforcement and other factors, many of which are outside our control.

We have loaned $15 million to an early stage company and may not be able to recoup our investment.

On March 4, 2015, we entered into an option agreement with eNeura, Inc. (“eNeura”), a privately held medical technology company that is developing devices for the treatment of migraines. The option agreement provided us with an exclusive option until September 2016 to acquire eNeura, which we ultimately did not exercise. In consideration for the option, (i) we paid a non-refundable $0.3 million fee to eNeura, and (ii) we loaned eNeura $15 million pursuant to a convertible, secured promissory note that was issued to us, which note matures on March 4, 2019.

eNeura is using the proceeds of our loan to fund product development work related to its business and to fund its ongoing operations and no assurance can be made that eNeura’s business will ultimately be successful. Although the promissory note is secured by many of eNeura’s assets (including its intellectual property assets), no assurance can be made that eNeura will be able to repay the promissory note when due in the event that the promissory note does not convert to equity. In such an event, we could lose all or a substantial portion of our $15 million loan investment. In addition, if a change in control of eNeura (generally defined as a third-party acquisition of fifty percent or more of eNeura’s voting equity or all or substantially all of eNeura’s assets) occurs prior to the maturity date on March 4, 2019, the eNeura Note will automatically convert into preferred stock of eNeura, and the value of such preferred stock could be less than the principal amount of the note.

Currently, we do not expect to collect the complete principal and interest on March 4, 2019 and are in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security.

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or earn revenue in currencies other than the U.S. Dollar, any change in the values of those foreign currencies relative to the U.S. Dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have potential foreign exchange exposure. The fluctuations of foreign exchange rates during 2018 have had a favorable impact of $2.3 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

Our global operations may expose us to tax risks

We are subject to taxes in the U.S. and numerous foreign jurisdictions. Significant judgment and interpretation of tax laws are required to estimate our tax liabilities. Tax laws and rates in various jurisdictions may be subject to significant change as a result of political and economic conditions. Our effective income tax rate could be adversely affected by changes in those tax laws; changes in the mix of earnings among tax jurisdictions; changes in the valuation of our deferred tax assets and liabilities; and the resolution of matters arising from tax audits.

Certain of our subsidiaries sell products directly to other Orthofix subsidiaries or provide marketing and support services to other Orthofix subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates, and we must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Tax authorities in these jurisdictions may challenge our treatment of such intercompany transactions. If we are unsuccessful in defending our treatment of intercompany transactions, we may be subject to additional tax liability or penalty, which could adversely affect our profitability.

*Our subsidiaries, Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. maintain a $125 million secured revolving credit facility secured by a pledge of substantially all of our property.*

On August 31, 2015, the Company, through its subsidiaries, Orthofix Holdings, Inc. and Victory Medical Limited (collectively the "Borrowers"), entered into a credit agreement (the "Credit Agreement") providing for a five-year secured revolving credit facility of $125 million. On December 8, 2017, the Company amended the Credit Agreement and the primary provision of the Credit Agreement to be amended, among other things, was to add the Company's subsidiary, Orthofix International B.V. as a Borrower, Guarantor, and a loan party. On July 31, 2018, the Company amended and restated the Credit Agreement in connection with the Domestication of the Company from a Curaçao company to a Delaware corporation.

.

The Company and certain of its existing and future U.S., U.K., and Netherlands domiciled subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries.

The Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions. In addition, the Credit Agreement contains financial covenants requiring us on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the facility may be accelerated and/or the lenders' commitments terminated.

We believe that we are in compliance with the negative covenants, and there were no events of default, at December 31, 2018 (and in prior periods). However, there can be no assurance that the Company would be able to meet such financial covenants in future fiscal quarters. The failure to do so could result in an event of default under such agreement, which could have a material adverse effect on our financial position in the event that we have significant amounts drawn under the facility at such time.

**Item 1B.** Unresolved Staff Comments

None.

**Item 2.** Properties

Our principal facilities as of December 31, 2018 are as follows:

| Facility | Location | Approx. Square Feet | Ownership |
|---|---|---|---|
| Manufacturing, warehousing, distribution, research and development, and | Lewisville, TX | 140,000 | Leased |

| | | | |
|---|---|---|---|
| administrative facility for Corporate and all reporting segments<br>Manufacturing, warehousing, distribution, research and development, and | | | |
| administrative facility for Spinal Kinetics<br>Research and development, component manufacturing, quality control and | Sunnyvale, CA | 25,000 | Leased |
| training facility for fixation products and sales management, distribution | | | |
| and administrative facility for Italy | Verona, Italy | 38,000 | Owned |
| International distribution center for Orthofix products | Verona, Italy | 18,000 | Leased |
| Mechanical workshop for Orthofix products | Verona, Italy | 9,000 | Leased |
| Sales management, distribution and administrative facility for United Kingdom | Maidenhead, England | 8,100 | Leased |
| Sales management, distribution and administrative facility for Brazil | São Paulo, Brazil | 22,000 | Leased |
| Sales management, distribution and administrative facility for France | Arcueil, France | 8,500 | Leased |
| Sales management, distribution and administrative facility for Germany | Ottobrunn, Germany | 18,300 | Leased |

**Item 3.** Legal Proceedings

For a description of our material pending legal proceedings, refer to Note 13 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

**Item 4.** Mine Safety Disclosures

Not applicable.

**PART II**

**Item 5.** Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "OFIX." As of February 22, 2019, we had 361 holders of record of our common stock. The closing price of our common stock on February 22, 2019 was $65.51. The following table shows the high and low sales prices for our common stock for each of the two most recent fiscal years.

| | High | Low |
|---|---|---|
| 2017 | | |
| First Quarter | $40.37 | $33.51 |
| Second Quarter | 46.86 | 36.10 |
| Third Quarter | 50.40 | 42.68 |
| Fourth Quarter | 56.53 | 47.27 |
| 2018 | | |
| First Quarter | $61.00 | $51.01 |
| Second Quarter | 61.86 | 51.38 |
| Third Quarter | 61.98 | 50.41 |
| Fourth Quarter | 63.57 | 48.00 |

Dividends

We have not paid dividends to holders of our common stock in the past and have no present intention to pay dividends in the foreseeable future. Additionally, we have restrictions on the ability to pay dividends in certain cirucmstances pursuant to our Amended Credit Agreement. We currently intend to retain all of our consolidated earnings to finance the continued growth of our business.

In the event that we decide to pay a dividend to holders of our common stock in the future with dividends received from our subsidiaries, we may, based on prevailing rates of taxation, be required to pay additional withholding and income tax on such amounts.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2018.

Performance Graph

The following performance graph is not deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C or to the liabilities of Section 18 of the Exchange Act. This information will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent we specifically incorporate this information by reference.

The graph below compares the five-year total shareholder return on Orthofix common stock with the returns of two indexes: the Nasdaq Stock Market and Nasdaq stocks for surgical, medical, and dental instruments and supplies. The graph assumes that you invested $100 in Orthofix Common Stock and in each of the indexes on December 31, 2013. Points on the graph represent the performance as of the last business day of each of the years indicated.

**Item 6.** Selected Financial Data

The following selected financial data has been derived from our audited consolidated financial statements.

| | Year ended December 31, | | | | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands, except margin and per share data) | 2018 | 2017 | 2016 | 2015 | 2014 |
| Consolidated operating results | | | | | |
| Net sales | $453,042 | $433,823 | $409,788 | $396,489 | $402,277 |
| Gross profit | 356,414 | 340,786 | 321,935 | 309,964 | 303,365 |
| Gross margin | 79 % | 79 % | 79 % | 78 % | 75 % |
| Operating income (1) | 30,094 | 40,811 | 21,067 | 9,225 | 17,136 |
| Net income (loss) from continuing operations | 13,811 | 7,291 | 3,497 | (2,342) | (3,744) |
| Net loss from discontinued operations | — | (1,068) | (441) | (467) | (4,793) |
| Net income (loss) (2) | $13,811 | $6,223 | $3,056 | $(2,809) | $(8,537) |
| Net income (loss) per common share – basic | | | | | |
| Net income (loss) from continuing operations | $0.73 | $0.40 | $0.19 | $(0.12) | $(0.20) |
| Net loss from discontinued operations | — | (0.06) | (0.02) | (0.03) | (0.26) |
| Net income (loss) | $0.73 | $0.34 | $0.17 | $(0.15) | $(0.46) |
| Net income (loss) per common share – diluted | | | | | |
| Net income (loss) from continuing operations | $0.72 | $0.39 | $0.19 | $(0.12) | $(0.20) |
| Net loss from discontinued operations | — | (0.05) | (0.02) | (0.03) | (0.26) |
| Net income (loss) | $0.72 | $0.34 | $0.17 | $(0.15) | $(0.46) |

(1) Includes the following:

- Legal, accounting, and other professional fees incurred in 2018, 2017, 2016, 2015, and 2014 of $1.1 million, $3.4 million, $2.0 million and $9.1 million, and $15.6 million, respectively, in connection with the accounting review and restatements through March 2015 and legal fees associated with the SEC Investigation, Securities Class Action Complaint and Brazil subsidiary compliance review. In addition, the Company received an insurance settlement related to these matters of approximately $6.1 million in 2017
- Charges related to U.S. Government resolutions in 2016 of $14.4 million

(2) Dividends have not been paid in any of the years presented

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2015 | 2014 |
| Consolidated financial position | | | | | |
| Total assets | $466,641 | $405,354 | $372,103 | $400,222 | $392,956 |
| Long-term debt | — | — | — | — | — |
| Shareholders' equity | 335,397 | 296,608 | 263,477 | 290,311 | 299,627 |

**Item 7.** Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with "Forward-Looking Statements" and our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report.

Executive Summary

Our products are distributed by our sales representatives and distributors in over 70 countries.

Notable highlights and accomplishments in 2018 include the following:

- Net sales were $453.0 million, an increase of 4.4% on a reported basis and 3.9% on a constant currency basis.
- Net income from continuing operations was $13.8 million, an increase of 89.4% from the prior year.
- Non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, was $150.9 million, an increase of 5.9% from the prior year.

Results of Operations

The following table presents certain items in our consolidated statements of income as a percent of net sales:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (%) | (%) | (%) |
| Net sales | 100.0 | 100.0 | 100.0 |
| Cost of sales | 21.3 | 21.4 | 21.4 |
| Gross profit | 78.7 | 78.6 | 78.6 |
| Sales and marketing | 45.4 | 45.7 | 44.2 |
| Non-GAAP net margin | 33.3 | 32.8 | 34.3 |
| General and administrative | 18.7 | 16.6 | 18.7 |
| Research and development | 7.3 | 6.9 | 7.0 |
| Changes in fair value of contingent consideration | 0.7 | — | — |
| Charges related to U.S. Government resolutions | — | — | 3.6 |
| Operating income | 6.6 | 9.4 | 5.1 |
| Net income from continuing operations | 3.0 | 1.7 | 0.9 |
| Net loss from discontinued operations | — | (0.3) | (0.2) |
| Net income | 3.0 | 1.4 | 0.7 |

Net Sales by Reporting Segment

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

| | | | | Percentage Change | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2018/2017 | | 2017/2016 | |
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | Reported | Constant Currency | Reported | Constant Currency |
| Bone Growth Therapies | $195,252 | $185,900 | $176,561 | 5.0 % | 5.0 % | 5.3 % | 5.3 % |
| Spinal Implants | 91,658 | 81,957 | 72,632 | 11.8 % | 11.9 % | 12.8 % | 12.7 % |
| Biologics | 59,684 | 62,724 | 57,912 | -4.8 % | -4.8 % | 8.3 % | 8.3 % |
| Orthofix Extremities | 106,448 | 103,242 | 102,683 | 3.1 % | 0.9 % | 0.5 % | -0.9 % |
| Net sales | $453,042 | $433,823 | $409,788 | 4.4 % | 3.9 % | 5.9 % | 5.5 % |

Bone Growth Therapies

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

2018 Compared to 2017

Net sales increased $9.4 million or 5.0%

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

2017 Compared to 2016

Net sales increased $9.3 million or 5.3%

- Increased as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society ("NASS") coverage recommendation and the launch of our next generation products and Stim on Track

Spinal Implants

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

2018 Compared to 2017

Net sales increased $9.7 million or 11.8%

- Increase of $8.7 million driven by international sales of M6 Artificial Discs subsequent to our acquisition of Spinal Kinetics, which closed during the second quarter of 2018
- Increase of 3.4% in U.S. sales due to the annualized sales of new distributor partners added during 2017 and from the uptake of recent product introductions
- Decrease in legacy international sales, primarily as a result of disruption to our distribution in our Australian and German subsidiaries

2017 Compared to 2016

Net sales increased $9.3 million or 12.8%

- Increase of 20.6% in U.S. sales due to the addition of new distributor partners in the last several quarters; the uptake of recent product introductions, including our PTC family product lines and Cetra; and improved legacy distributor engagement
- Despite strong performance in certain locations, such as Australia, year-over-year international sales decreased largely due to a decrease in order volumes from international stocking distributors

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.

2018 Compared to 2017

Net sales decreased $3.0 million or 4.8%

- Decrease of 6.1% primarily driven by the contractual reduction during the first quarter of 2018 in the amount we receive for marketing service fees for Trinity tissues from MTF Biologics ("MTF")
- Volume for Trinity tissues increased by 3.3%, partially offset by low single-digit pricing pressure in the market

2017 Compared to 2016

Net sales increased $4.8 million or 8.3%

- Increase in volume for our Trinity products primarily driven by the addition of new distributors over the prior year
- Benefit from improving performance from our national distribution partner and the reactivation of a national hospital contract

Orthofix Extremities

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

2018 Compared to 2017

Net sales increased $3.2 million or 3.1%

- Increase largely due to the change in foreign currency exchange rates, which had a positive impact on net sales of $2.3 million
- Increase of $1.4 million within the U.S. due to continued distribution expansion and adoption of our TrueLok products
- Increase in international sales of $2.8 million, excluding the impact of changes in foreign currency exchange rates, due to continued expansion of our distributors and growth in European subsidiaries
- Partially offset by an expected decrease of $3.3 million in Brazil as a result of our Orthofix Extremities restructuring during 2017

2017 Compared to 2016

Net sales increased $0.6 million or 0.5%

- Growth in the U.S. and the U.K., largely due to the continued adoption of our TL-HEX product line
- Increase of $1.5 million attributable to a favorable impact from foreign currency translation
- Partially offset by a decrease of $3.6 million related to our Orthofix Extremities restructuring, which consisted of the divestiture of a non-core business in the U.K. and a reduction in sales in Brazil and Puerto Rico as we converted from a direct sales model to the use of stocking distributors
- And additionally offset by a decrease in cash collections from specific international stocking distributors whose revenue is recognized upon cash receipt

Gross Profit and Non-GAAP Net Margin

| | | | | Percentage Change | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2018/2017 | 2017/2016 |
| Gross profit | $356,414 | $340,786 | $321,935 | 4.6% | 5.9% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Sales and marketing | 205,527 | | 198,370 | | 181,287 | | 3.6% | 9.4 % |
| Non-GAAP net margin | $150,887 | | $142,416 | | $140,648 | | 5.9% | 1.3 % |
| | | | | | | | | |
| Gross margin | 78.7 | % | 78.6 | % | 78.6 | % | 0.1% | 0.0 % |
| Non-GAAP net margin | 33.3 | % | 32.8 | % | 34.3 | % | 0.5% | -1.5 % |

37

2018 Compared to 2017

Non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, increased $8.5 million

- Gross profit increased $15.6 million
  - Primarily due to the growth in net sales with gross margin improving slightly from 78.6% in 2017 to 78.7% in 2018
    - Partially offset by the addition of Spinal Kinetics acquisition-related inventory fair market value adjustments of $1.4 million within the Spinal Implants reporting segment
- Sales and marketing expense increased $7.2 million
  - Primarily due to the increase in net sales, with sales and marketing expenses as a percentage of net sales improving slightly to 45.4% of net sales in 2018 compared to 45.7% in 2017

2017 Compared to 2016

Non-GAAP net margin increased $1.8 million

- Gross profit increased $18.9 million
  - Largely driven by the increase in net sales for each of our reporting segments, as gross margin remained relatively flat
  - Partially offset by an increase of $0.2 million in expense relating to our Orthofix Extremities and U.S. restructurings
- Sales and marketing expense increased $17.1 million
  - Primarily relating to higher commission expenses in 2017, relating to geographic mix in Orthofix Extremities and higher commission rates from new distributors for Biologics and Spinal Implants, and an increase in other compensation costs as a result of the increase in net sales

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

| | | | | Percentage Change | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2018/2017 | 2017/2016 |
| Bone Growth Therapies | $86,252 | $77,369 | $75,469 | 11.5 % | 2.5 % |
| Spinal Implants | 7,628 | 8,730 | 8,650 | -12.6% | 0.9 % |
| Biologics | 26,298 | 25,692 | 26,891 | 2.4 % | -4.5 % |
| Orthofix Extremities | 31,391 | 31,071 | 30,526 | 1.0 % | 1.8 % |
| Corporate | (682) | (446) | (888) | 52.9 % | -49.8 % |
| Non-GAAP net margin | $150,887 | $142,416 | $140,648 | 5.9 % | 1.3 % |

General and Administrative Expense

| | | | | Percentage Change | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2018/2017 | 2017/2016 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| General and administrative | $84,506 | | $71,905 | | $76,409 | | 17.5% | | -5.9 | % |
| As a percentage of net sales | 18.7 | % | 16.6 | % | 18.7 | % | 2.1 | % | -2.1 | % |

2018 Compared to 2017

General and administrative expense increased $12.6 million

- Increase of $6.3 million in expenses associated with strategic investments, such as our due diligence and integration efforts in connection with the Spinal Kinetics acquisition and expenditures related to the Domestication

- Increase in share-based compensation expense of $5.5 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in the timing of our annual grants to executives and key personnel
- Increase of $1.8 million associated with legal judgments and settlements, including previous SEC and FCPA matters, largely as a result of the receipt of a favorable insurance settlement in 2017 of approximately $6.1 million associated with prior costs incurred
- Increase of $0.9 million relating to the amortization of acquired intangibles associated with the Spinal Kinetics acquisition
- Partially offset by decreases in certain compensation-related costs, including bonus incentives and benefits

2017 Compared to 2016

General and administrative expense decreased $4.5 million

- We received a favorable insurance settlement in 2017 of approximately $6.1 million associated with prior costs incurred related to SEC and FCPA matters
- Decrease of $3.6 million from a reduction in Project Bluecore expenses, as the project was completed in 2016
- Decrease in share-based compensation expense of $3.5 million, largely driven by a net decrease in expense attributable to performance-based and market-based awards
- Core expense reductions through savings in other professional fees of $2.0 million
- Partially offset by an increase in spending of $5.7 million for evaluation of strategic investments
- Further offset by an unfavorable change related to legal settlements of $3.5 million, largely as a result of a favorable commercial litigation settlement received in 2016 of $3.0 million
- Pursuant to our settlement of the SEC Investigation and FCPA matters in Brazil, we agreed to retain an independent compliance consultant for one year to review and test the Company's FCPA compliance program, which began in March 2017 and resulted in an increase in expense of $1.8 million

Research and Development Expense

| | | | | Percentage Change | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2018/2017 | 2017/2016 |
| Research and development | $33,218 | $29,700 | $28,803 | 11.8% | 3.1% |
| As a percentage of net sales | 7.3% | 6.9% | 7.0% | 0.4% | -0.1% |

2018 Compared to 2017

Research and development expense increased $3.5 million

- Increase in research and development costs largely attributable to the Spinal Kinetics acquisition and the regulatory efforts associated with the U.S. Food and Drug Administration ("FDA") premarket approval of the M6 Artificial Cervical Disc

2017 Compared to 2016

Research and development expense increased $0.9 million

- Increase in costs associated with clinical trials of $0.7 million, primarily due to invested resources to identify potential new indications for our PEMF technology, such as for osteoarthritis of the knee or as an adjunct to rotator cuff repair

- Increase in costs largely attributable to the initiation of the Company's U.S. restructuring plan in 2017, which primarily affected our corporate shared services, and resulted in an increase in expense of $0.5 million

39

***Changes in Fair Value of Contingent Consideration***

| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | Percentage Change 2018/2017 | Percentage Change 2017/2016 |
|---|---|---|---|---|---|
| Changes in fair value of contingent consideration | $3,069 | $— | $— | — | — |
| As a percentage of net sales | 0.7 % | 0.0 % | 0.0 % | 0.7 % | 0.0 % |

2018 Compared to 2017

The fair value of contingent consideration increased $3.1 million

- Changes relate to the fair value of the potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition. For additional information, see Note 3 of the Notes to the Consolidated Financial Statements.

Charges Related to U.S. Government Resolutions

| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | Percentage Change 2018/2017 | Percentage Change 2017/2016 |
|---|---|---|---|---|---|
| Charges related to U.S. Government resolutions | $— | $— | $14,369 | — | -100.0 % |
| As a percentage of net sales | 0.0 % | 0.0 % | 3.6 % | 0.0 % | -3.6 % |

2017 Compared to 2016

We recorded $14.4 million in 2016 for our settlements with the Division of Enforcement of the SEC related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil. For additional information, see Note 13 of the Notes to the Consolidated Financial Statements.

Non-operating Income (Expense)

| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | Percentage Change 2018/2017 | Percentage Change 2017/2016 |
|---|---|---|---|---|---|
| Interest income (expense), net | $(828) | $(416) | $763 | 99.0 % | -154.5 % |
| Other expense, net | (6,381) | (4,004) | (2,806) | 59.4 % | 42.7 % |

Non-operating income and expense largely consists of interest income and expense, transaction gains and losses from changes in foreign currency exchange rates, changes in fair value related to our equity holdings in Bone Biologics, Inc. ("Bone Biologics"), and other-than-temporary impairments on the eNeura debt security. Interest income in 2016 was primarily from our eNeura debt security; however, we discontinued recognizing interest income on the debt security in 2017. Foreign exchange gains and losses are primarily a result of several of our foreign subsidiaries holding trade and intercompany payables or receivables in currencies (most notably the U.S. Dollar) other than their functional currency.

2018 Compared to 2017

Other income (expense), net, decreased $2.4 million

- Decrease of $5.3 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of $3.3 million in 2018 compared to a gain of $1.9 million in 2017
- Decrease of $3.1 million from impairments and changes in fair value relating to our equity holdings and warrants in Bone Biologics common stock
- Partially offset by an increase of $5.6 million associated with an other-than-temporary impairment on the eNeura debt security in 2017 that did not recur in 2018

2017 Compared to 2016

Other income (expense), net, decreased $1.2 million

- Decrease of $2.9 million associated with other-than-temporary impairments on the eNeura debt security, as we recorded impairments of $5.6 million and $2.7 million before taxes in 2017 and 2016, respectively

- Partially offset by an increase of $2.0 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement gain of $1.9 million in 2017 compared to a loss of less than $0.1 million in 2016

Income Taxes

| | | | | Percentage Change | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 | 2018/2017 | 2017/2016 |
| Income tax expense | $9,074 | $29,100 | $15,527 | -68.8% | 87.4 % |
| Effective tax rate | 39.7 % | 80.0 % | 81.6 % | -40.3% | -1.6 % |

2018 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the decrease in income before income taxes, the reduction of the US statutory tax rate from 35% to 21%, and the 2017 charge from recording the impact of the Tax Cuts and Jobs Act (the “Tax Act”) that did not recur in 2018. The primary factors affecting our effective tax rate for 2018 are as follows:

- Current period losses in jurisdictions where we do not currently receive a tax benefit
- State taxes and foreign income taxed at differing rates
- Benefits of deductible equity compensation in excess of financial statement impact

On December 22, 2017, the Tax Act was signed into law, making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. We calculated our best estimate of the impact of the Tax Act in our 2017 year end income tax provision in accordance with our understanding of the Tax Act and guidance available as of the date of that filing. As a result, we recorded $8.3 million of additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. This provisional amount related to remeasurement of certain deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future was $8.6 million. The provisional amount related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings was zero. We also recorded a benefit of $0.3 million related to an income tax liability recorded in 2016 related to repatriation of earnings from our subsidiary in Puerto Rico. We have finalized the accounting for the Tax Act, which resulted in an additional benefit of $0.6 million in the first quarter of 2018 and minimal adjustments in the fourth quarter.

2017 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the increase in income before income taxes, partially offset by the charge related to recording the impact of the Tax Act. The primary factors affecting our effective tax rate for 2017 are as follows:

- The charge related to recognizing the impact of the Tax Act
- Increases in unrecognized tax benefits
- Current period losses in jurisdictons where we do not currently receive a tax benefit

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2018 was $72.2 million compared to $81.2 million at December 31, 2017.

| | Year Ended December, 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Change |
| Net cash from operating activities | $49,918 | $38,972 | $10,946 |
| Net cash from investing activities | (60,998) | (16,474) | (44,524) |
| Net cash from financing activities | 2,993 | 3,538 | (545) |
| Effect of exchange rate changes on cash and restricted cash | (881) | 1,180 | (2,061) |
| Net change in cash, cash equivalents, and restricted cash | $(8,968) | $27,216 | $(36,184) |

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.

| | Year Ended December, 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2018 | 2017 | Change |
| Net cash from operating activities | $49,918 | $38,972 | $10,946 |
| Capital expenditures | (15,256) | (16,948) | 1,692 |
| Free cash flow | $34,662 | $22,024 | $12,638 |

Operating Activities

Cash flows from operating activities increased $10.9 million

- Increase in net income of $7.6 million
- Net decrease of $21.2 million for non-cash gains and losses, primarily related to deferred income taxes, share-based compensation expense, an other-than-temporary impairment incurred relating to the eNeura debt security in 2017, and loss on the valuation of our investments in Bone Biologics in 2018
- Net increase of $24.6 million relating to changes in working capital, primarily attributable to changes in inventories, as a result of improved inventory management initiatives put into place in 2017 and 2018

Two of our primary working capital accounts are trade accounts receivable and inventory. Day's sales in receivables were 63 days at December 31, 2018 compared to 53 days at December 31, 2017, with the increase largely attributable to our adoption of Accounting Standards Update ("ASU") 2014-09 in 2018. Inventory turns were 1.3 times as of December 31, 2018 compared to 1.1 times at December 31, 2017, primarily resulting from improved inventory management initatives put into place in 2017 and 2018.

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

In November 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. We adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in an increase in net cash from operating activities of $2.5 million for the year ended December 31, 2018 and a decrease in net cash from operating activities of $14.4 million for the year ended December 31, 2017.

Investing Activities

Cash flows from investing activities decreased $44.5 million

- Decrease of $44.3 million associated with cash paid in relation to the Spinal Kinetics acquisition, net of cash acquired, which closed on April 30, 2018
- Decrease of $0.9 million associated with the acquisition of certain intangible assets in transactions with former distributors in 2018
- Decrease of $0.5 million due to our additional investment in Bone Biologics during 2018
- Decrease of $0.5 million due to proceeds received in 2017 upon the maturity of certain time-based deposits
- Partially offset by a reduction in capital expenditures of $1.7 million

Financing Activities

Cash flows from financing activities decreased $0.5 million

- Decrease in net proceeds of $0.3 million from the issuance of common shares
- Decrease of $0.2 million related to the payment of debt issuance costs and other financing activities

*Credit Facilities*

On August 31, 2015, we entered into a Credit Agreement with JPMorgan Chase Bank, N.A. ("JPMorgan"), the Administrative Agent, and certain lenders party thereto, which provided a five year $125 million secured revolving credit facility.

On December 8, 2017, we amended the Credit Agreement with JPMorgan. The primary provision of the amendment, among other things, was to add our subsidiary, Orthofix International B.V., as a Borrower, Guarantor, and a loan party. In addition, two of our subsidiaries, Orthofix Limited and Orthofix II B.V. were also added as Guarantors and loan parties.

On July 31, 2018, we amended and restated the Credit Agreement with JPMorgan and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement ("Amended Credit Agreement"). The Amended Credit Agreement is substantially the same as the previous Credit Agreement, except for certain amendments to, among other things, (i) effectuate the Domestication of the Company from a Curaçao company to a Delaware corporation, (ii) limit the pledge by the Company and each domestic subsidiary of the Company of equity interests in their respective first tier foreign subsidiaries to 65% of the voting interests in such foreign subsidiaries, (iii) limit the guarantee and joint and several obligations of each subsidiary guarantor that is a foreign subsidiary so that such foreign subsidiary guarantors are only providing guarantees, or are jointly and severally obligated, for obligations of other foreign subsidiaries, and (iv) limit the secured obligations that are secured by collateral provided by subsidiary guarantors that are foreign subsidiaries to secured obligations of foreign subsidiaries.

Borrowings under the Amended Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions). As of December 31, 2018, we have not made any borrowings under the credit facility. For additional information regarding the credit facility, see Note 10 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

We had no borrowings and an unused available line of credit of €5.8 million ($6.7 million and $7.0 million) at December 31, 2018 and 2017, respectively, on our Italian line of credit. This unsecured line of credit provides us the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

Other

For information regarding Contingencies, see Note 13 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Spinal Kinetics Acquisition and Contingent Consideration

As consideration for the Spinal Kinetics acquisition, we agreed to pay an aggregate of $45.0 million in cash, subject to certain adjustments, upon closing plus milestone payments in the future of up to $60.0 million in cash. We closed on the acquisition on April 30, 2018 and paid the $45.0 million of cash, adjusted for certain items, due at close with cash on hand. The milestone payments include (i) up to $15.0 million if the FDA grants approval of Spinal Kinetics' M6-C artificial cervical disc (the "FDA Milestone") and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The fair value of the contingent consideration arrangement as of December 31, 2018 was $28.6 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. Approximately $13.6 million of this liability is included within other current liabilities and $15.0 million is included within other long-term liabilities. For additional discussion of this matter, see Note 3 of the Notes to the Consolidated Financial Statements.

On February 6, 2019, we obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. This approval triggered our payment obligation of $15.0 million of contingent consideration attributable to the Spinal Kinetics purchase price. We had accrued a liability of $13.6 million within other current liabilities as of December 31, 2018 related to this milestone payment and paid the $15.0 million FDA Milestone payment on February 14, 2019 from cash on hand.

Debt Security

In 2015, we loaned $15.0 million to eNeura, a privately held medical technology company that is developing devices for the treatment of migraines, pursuant to a Convertible Promissory Note (the “eNeura Note”). The eNeura Note accrues interest at 8.0% and will mature on March 4, 2019, with interest due when the eNeura Note matures. The security is collateralized by eNeura’s intellectual property in the event of default or nonpayment.

Currently, we do not expect to collect the complete principal and interest on March 4, 2019 and are in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security. For additional discussion of this matter, see Note 8 of the Notes to the Consolidated Financial Statements.

***Unremitted Foreign Earnings***

Prior to the Domestication, as an entity incorporated in Curaçao, "foreign earnings" referred to both U.S. and non-U.S. earnings. As a result of the Domestication, only income sourced outside of the U.S. is considered unremitted foreign earnings. Unremitted foreign earnings decreased from $335.7 million at December 31, 2017 to $50.4 million at December 31, 2018. The substantial decrease is due to the elimination of US accumulated earnings and other impacts as a result of the Domestication. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. Our investment in foreign subsidiaries continues to be indefinite in nature, however, we may periodically repatriate a portion of these earnings to the extent that we do not incur additional tax liability.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2018:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| (U.S. Dollars, in thousands) | Total | 2019 | 2020 - 2022 | 2023 | 2024 and thereafter |
| Operating leases | $24,922 | $3,330 | $8,493 | $1,727 | $ 11,372 |
| Inventory purchase commitments (1) | 66 | 66 | — | — | — |
| Total (2)(3) | $24,988 | $3,396 | $8,493 | $1,727 | $ 11,372 |

(1) We have inventory purchase commitments with third-party manufacturers. Due to the uncertainty of our future purchasing requirements, obligations under these agreements are included in the preceding table at the amount committed through December 31, 2018, all of which are due in 2019.

(2) As a result of obtaining FDA approval for the M6-C artificial cervical disc on February 6, 2019, we are required to make a $15.0 million payment in 2019 related to the achievement of the FDA milestone, which we paid on February 14, 2019. In addition, we may be required to make additional 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; however, we are unable to reliably estimate the timing of cash settlement, if any, related to the revenue-based milestone payments.

(3) We may be required to make payments related to our uncertain tax positions. However, we are unable to reliably estimate the timing of cash settlement, if any, with the respective taxing authorities. Accordingly, unrecognized tax benefits, including interest and penalties, of $28.1 million as of December 31, 2018 have been excluded from the contractual obligations table above. For further information, see Note 19 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Off-balance Sheet Arrangements

As of December 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. In addition, we do not consider the backlog of firm orders to be material.

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. On an ongoing basis, we evaluate these

estimates, which are based on historical experience and various other assumptions that management believe to be reasonable under the circumstances at that point in time. Actual results may differ, significantly at times, from these estimates.

We believe the estimates described below are the most critical in preparing our consolidated financial statements. We have reviewed these critical accounting estimates with the Audit Committee of the Board of Directors.

Revenue Recognition

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

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

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors, such as Medicare, in connection with the sale of our stimulation products, we recognize revenue when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

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

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.

Orthofix Extremities and Spinal Implants products are distributed world-wide, with U.S. sales largely comprised of commercial revenue and international sales derived from commercial sales and through stocking distributor arrangements.

Commercial revenue is largely related to the sale of our Spinal Implants and Orthofix Extremities products to 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 ASU 2014-09, *Revenue from Contracts with Customers* ("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.

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. We believe our allowance for doubtful accounts is sufficient to cover customer credit risks; however, a 10% change in our allowance for doubtful accounts as of December 31, 2018 would result in an increase or decrease to sales and marketing expense of $0.7

million. Additionally, we believe our estimate to establish contractual allowances is sufficient to cover customer credit risks; however, a 10% change in our reserve for contractual allowances as of December 31, 2018 would result in an increase or decrease to net sales of $0.6 million. 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, non-GAAP net margin, operating income, net income, and trade accounts receivable.

Inventory Allowances

Reserves for excess, slow moving, and obsolete inventory are calculated as the difference between the cost of inventory and market value, and are based on assumptions and judgments about new product launch periods, overall product life cycles, forecasted demand, and market conditions. In the event of a decrease in demand for our products, or a higher incidence of inventory obsolescence, we could be required to increase our inventory reserves, which would increase cost of sales and decrease gross profit. Our inventory allowance is a “critical accounting estimate” because changes in the assumptions used to develop the estimate could materially affect key financial measures, including gross profit, non-GAAP net margin, operating income, net income, and inventory. We regularly evaluate our exposure for inventory write-downs.  If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

Valuation of Intangible Assets

Our intangible assets are comprised primarily of patents, acquired or developed technology, licensing arrangements, trademarks, and in-process research and development (“IPR&D”). We make significant judgments in relation to the valuation of intangible assets resulting from business combinations or asset acquisitions. Intangible assets acquired in a business combination that are used for IPR&D activities are considered to have indefinite lives until the completeion or abandonment of the associated project. Upon reaching the end of the revelant project, we will either amortize the acquired IPR&D over its estimated useful life or expense the acquired IPR&D should the project be unsuccessful with no future alternative use.

Significant judgment is required related to the forecasting of future operating results within our discounted cash flow valuation models to determine the valuation of intangible assets. Key assumptions include the anticipated useful lives of acquired intangibles, the projected cash flows associated with each intangible asset, the estimated probability of success for acquired IPR&D projects, and projected growth rates and discount rates. It is possible that significant changes in plans or assumptions may affect the recoverability of these assets and could potentially result in impairment.

Goodwill

Our goodwill represents the excess of cost over fair value of net assets acquired from business combinations. The determination of the value of goodwill and intangible assets arising from business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired.

We test goodwill at least annually for impairment, and between annual tests if indicators of potential impairment exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. Assessing goodwill impairment involves a high degree of judgment due to the estimates and assumptions used. We believe the estimates and assumptions involved in the impairment assessment to be critical because significant changes in such estimates and assumptions could materially affect key financial measures, including net income.

In the fourth quarters of 2018 and 2017, we performed a qualitative assessments for our annual goodwill impairment analysis, which did not result in any impairment charge. This qualitative analysis considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance and relevant entity-specific events. In the fourth quarter of 2016, we performed a quantitative impairment analysis that did not result in an impairment charge.

Fair Value Measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The two most significant items that are recorded at fair value are our eNeura debt security and contingent consideration attributable to the Spinal Kinetics acquisition.

The fair value of the eNeura debt security is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring us to develop our own assumptions. Some of the more significant unobservable inputs used in the fair value measurement of the eNeura debt security are the estimated likelihood of conversion to equity and the discount rate. Holding other

inputs constant, a decrease in our assumption for the likelihood of conversion to equity of 10% would result in an increase in fair value of the debt security of $1.9 million.

Further, we are required to determine whether any decline in the fair value below the cost basis of the eNeura debt security is other than temporary. In making this determination, we consider our intentions to hold or sell the security, whether it more likely than not that we will be required to sell the security before the recovery of its amortized cost basis, and our best estimate of the amount that we ultimately expect to collect from the security. The estimated amount we expect to collect is based upon significant unobservable inputs, requiring us to develop our own assumptions, including the probability of holding the security to maturity or converting the security to equity.

The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition, which must be achieved within five years of the acquisition date to be paid. The milestone payments include (i) up to $15.0 million for meeting 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.

We estimate the fair value of the contingent consideration attributable to the FDA Milestone using a probability-weighted discounted cash flow model. This fair value is based on significant inputs not observable in the market with key assumptions including our estimation of the probability and timing of obtaining FDA approval for the M6-C artificial cervical disc and the discount rate applied. Significant changes in these assumptions could result in a significantly higher or lower fair value. Holding other inputs constant, an increase in our estimate for probability of FDA approval as of December 31, 2018 by 5% would have resulted in an increase in the fair value of the contingent consideration of $0.7 million, whereas a decrease in our estimate of probability of FDA approval by 5% would have resulted in a decrease in the fair value of the contingent consideration of $0.7 million. On February 6, 2019, we obtained FDA approval, triggering our payment obligation of $15.0 million of contingent consideration attributable to the Spinal Kinetics purchase price.

The Company estimated the fair value of the potential future revenue-based milestone payments using a Monte Carlo simulation. This fair value measurement is based on significant inputs that are unobservable in the market, with key assumptions including the our forecasted future revenues for Spinal Kinetics, the discount rate applied, and assumptions for potential volatility of the forecasted revenue. Significant changes in these assumptions could result in a significantly higher or lower fair value. Holding other inputs constant, an increase in our forecasted future revenues by 5% would have resulted in an increase in the fair value of the contingent consideration of $1.8 million, whereas a decrease in our forecasted future revenues by 5% would have resulted in a decrease in the fair value of the contingent consideration by $1.7 million.

Our fair value measurements are a “critical accounting estimate” because changes in the assumptions used to develop the estimate could materially affect key financial measures.

Litigation and Contingent Liabilities

From time to time, we are parties to or targets of lawsuits, investigations and proceedings, including product liability, personal injury, patent and intellectual property, health and safety and employment and healthcare regulatory matters, which are handled and defended in the ordinary course of business. These lawsuits, investigations or proceedings could involve a substantial number of claims and could also have an adverse impact on our reputation and customer base. Although we maintain various liability insurance programs for liabilities that could result from such lawsuits, investigations or proceedings, we are self-insured for a significant portion of such liabilities.

We accrue for such claims when it is probable that a liability has been incurred and the amount can be reasonably estimated. The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that we consider in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, our experience in similar matters and the experience of other companies, the facts available to us at the time of assessment, and how we intend to respond, or have responded, to the proceeding, investigation or claim. Our assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where we are not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters

involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

Changes in the facts and circumstances associated with a claim could have a material impact on our results of operations and cash flows in the period that reserve estimates are recorded or revised. We believe our insurance coverage and reserves are sufficient to cover currently estimated exposures, but we cannot give any assurance that we will not incur liabilities in excess of recorded reserves or our present insurance coverage. Litigation and contingent liabilities are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including operating income and net income.

Tax Matters

We and each of our subsidiaries are taxed at the rates applicable within each of their respective jurisdictions. Our income tax expense, effective tax rate, deferred tax assets and deferred tax liabilities will vary according to the jurisdiction in which profits arise. Further, certain of our subsidiaries sell products directly to our other subsidiaries or provide administrative, marketing and support services to our other subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates. The tax authorities in such jurisdictions may challenge our treatments under residency criteria, transfer pricing provisions, or other aspects of their respective tax laws, which could affect our composite tax rate and provisions.

We sometimes engage in transactions in which tax consequences may be subject to uncertainty. We account for these uncertain tax positions in accordance with applicable accounting guidance, which requires significant judgment in assessing the estimated tax consequences of a transaction. We evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. We measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We re-evaluate our income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision.

We establish a valuation allowance when measuring deferred tax assets if it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future. This process requires significant judgment as we must project the current tax liability and estimate the deferred tax assets and liabilities into future periods, including net operating loss and tax credit carry forwards. In assessing the need for a valuation allowance, we consider recent operating results, availability of taxable income in carryback years, future reversals of taxable temporary differences, future taxable income projections (exclusive of reversing temporary differences) and all prudent and feasible tax planning strategies.

On December 22, 2017, Staff Accounting Bulletin No. 118 (“SAB 118”) was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we recorded $8.6 million of deferred tax expense in connection with the remeasurement of certain deferred tax assets and liabilities and the zero transition tax on the mandatory deemed repatriation of foreign earnings as a provisional amount and a reasonable estimate at December 31, 2017. Additional work was performed during 2018, including a more detailed analysis of our deferred tax assets and liabilities and our historical foreign

earnings as well as potential correlative adjustments. As a result, we recorded $0.6 million of tax benefit in the first quarter of 2018. The U.S. Treasury continues to promulgate proposed, temporary, and final regulations regarding the application the Tax Act. Any future adjustments that result of the application of these tax law changes will be relected in the quarter the guidance is issued.

Tax matters are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net income.

Share-based compensation

Determining the appropriate fair value model and calculating the fair value of employee stock awards requires estimates and judgments. Our share-based compensation is a “critical accounting estimate” because changes in the assumptions used to develop

estimates of fair value or the requisite service period could materially affect key financial measures, including gross profit, non-GAAP net margin, operating income, and net income.

We use the Black-Scholes valuation model to calculate the fair value of service-based stock options. The value is recognized as expense over the service period net of actual forfeitures. The expected term of options granted is estimated based on a number of factors, including the vesting and expiration terms of the award, historical employee exercise behavior for both options that are currently outstanding and options that have been exercised or are expired, the historical volatility of our common stock and an employee's average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. We estimate expected volatility based on the historical volatility of our stock.

We use the Monte Carlo valuation methodology to calculate the fair value of market-based stock options and stock units. The value is recognized as expense over the requisite service period and adjusted for forfeitures as they occur. The Monte Carlo methodology that we use to estimate the fair value of market-based options incorporates the possibility that the market condition may not be satisfied.

The fair value of performance-based restricted stock awards and stock units is calculated based upon the closing stock price at the date of grant. The value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest. Vesting probability is assessed based upon forecasted earnings and financial results and requires significant judgment.

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

The non-GAAP financial measures used in this Annual Report 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. Similarly, certain non-cash expenses, such as equity compensation expense, do not directly impact cash flows, but are part of total compensation costs accounted for under GAAP.

Constant Currency

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

**Item 7A.** Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can impact sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We may use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes.

We are exposed to interest rate risk in connection with our Revolving Credit Facility, which bears interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the Amended Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. As we do not have any balance outstanding associated with the Amended Credit Agreement as of December 31, 2018, this risk is currently minimal.

We believe that a concentration of credit risk related to our trade accounts receivable is limited because our customers are geographically dispersed and the end users are diversified across several industries. It is reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these customers operate, or other factors, could affect the future realization of these accounts receivable balances.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Brazilian Real, or British Pound. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro, Brazilian Real, or British Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. For the year ended December 31, 2018, we recorded a foreign currency loss of $3.3 million on the statement of income and comprehensive income resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. Dollar at exchange rates that fluctuate during the period. The U.S. Dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the years ended December 31, 2018 and 2017 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results. An analysis was performed to determine the sensitivity of our current year net sales and operating income to changes in foreign currency exchange rates. We determined that if the U.S. Dollar decreased in value by 10% relative to all foreign currencies of our international operations it would result in an increase in net sales of $8.6 million and an increase in operating income of $0.4 million. If the U.S. Dollar increased in value by 10% relative to all foreign currencies of our international operations it would result in a decrease in net sales of $8.6 million and a decrease in operating income of $0.4 million.

**Item 8.** Financial Statements and Supplementary Data

See “Index to Consolidated Financial Statements” on page F-1 of this Annual Report.

**Item 9.** Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

**Item 9A.** Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this Annual Report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Annual Report, our disclosure controls and procedures were effective.

**Management's Report on Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in the Exchange Act Rule 13a-15(f)). The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation of reliable financial statements for external purposes in accordance with U.S. GAAP. Because of the inherent limitations in any internal control, no matter how well designed, misstatements may occur and not be prevented or detected. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Further, the evaluation of the effectiveness of internal control over financial reporting was made as of a specific date, and continued effectiveness in future periods is subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may decline.

In connection with the preparation and filing of this Annual Report, the Company's management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework set forth in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company's management concluded that, as of December 31, 2018, the Company's internal control over financial reporting is effective based on the specified criteria. As permitted by the rules of the SEC, the Company's management excluded Spinal Kinetics from its annual assessment of the effectiveness of internal control over financial reporting for the year ended December 31, 2018, the year of acquisition. As of December 31, 2018, Spinal Kinetics' financial statements constituted approximately 17% and 21% of our total assets and net assets, respectively, approximately 2% of our revenues and a net loss of $5.8 million for the year ended December 31, 2018.

Ernst & Young has issued an audit report on the effectiveness of our internal control over financial reporting, which follows this report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2018 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders and the Board of Directors of Orthofix Medical Inc.

Opinion on Internal Control over Financial Reporting

We have audited Orthofix Medical Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Orthofix Medical Inc. (formerly Orthofix International N.V.) (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Spinal Kinetics, Inc., which is included in the 2018 consolidated financial statements of the Company and constituted approximately 17% and 21% of total and net assets, respectively, as of December 31, 2018 and 2% of revenues and a net loss of $5.8 million for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Spinal Kinetics, Inc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of income and comprehensive income, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 25, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Dallas, Texas

February 25, 2019

**Item 9B.** Other Information
Not applicable.

PART III

Information required by Items 10, 11, 12, 13 and 14 of Form 10-K is omitted from this Annual Report and will be filed in a definitive proxy statement or by an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report.

**Item 10.** Directors, Executive Officers and Corporate Governance
We will provide information that is responsive to this Item 10 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Information About Directors,” “Section 16 (a) Beneficial Ownership Reporting Compliance” and others possibly elsewhere therein. That information is incorporated in this Item 10 by reference.

**Item 11.** Executive Compensation
We will provide information that is responsive to this Item 11 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Executive Compensation,” and possibly elsewhere therein. That information is incorporated in this Item 11 by reference.

**Item 12.** Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
We will provide information that is responsive to this Item 12 regarding ownership of our securities by certain beneficial owners and our directors and executive officers, as well as information with respect to our equity compensation plans, in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the captions “Security Ownership of Certain Beneficial Owners and Management and Related Stockholders” and “Equity Compensation Plan Information,” and possibly elsewhere therein. That information is incorporated in this Item 12 by reference.

**Item 13.** Certain Relationships and Related Transactions, and Director Independence
We will provide information that is responsive to this Item 13 regarding transactions with related parties and director independence in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Certain Relationships and Related Transactions,” and “Director Independence” and possibly elsewhere therein. That information is incorporated in this Item 13 by reference.

**Item 14.** Principal Accountant Fees and Services
We will provide information that is responsive to this Item 14 regarding principal accountant fees and services in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Principal Accountant Fees and Services,” and possibly elsewhere therein. That information is incorporated in this Item 14 by reference.

54

PART IV

**Item 15.** Exhibits, Financial Statement Schedules

**(a)** Documents filed as part of report on Form 10-K

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements

See "Index to Consolidated Financial Statements" on page F-1 of this Form 10-K.

2. Financial Statement Schedules

No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

| Exhibit Number | Description |
|---|---|
| 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. (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and incorporated herein by reference). |
| 3.1 | Orthofix Medical Inc. Certificate of Incorporation (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference). |
| 3.2 | Orthofix Medical Inc. Bylaws (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference). |
| 4.1 | Form of Stock Certificate (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference). |
| 10.1 | Credit Agreement, dated as of August 31, 2015, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Current Report on Form 8-K filed September 1, 2015 and incorporated herein by reference). |
| 10.2 | First Amendment to Credit Agreement dated as of March 7, 2016 but effective as of February 29, 2016, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference). |
| 10.3 | Second Amendment to Credit Agreement dated as of December 8, 2017, among Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. as borrowers, Orthofix International N.V. and |

| | |
|---|---|
| | certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and incorporated herein by reference). |
| 10.4 | First Amended and Restated Credit Agreement, dated as of July 31, 2018, among Orthofix Holdings, Inc., Victory Medical Limited, Orthofix International B.V., Orthofix Medical Inc. and certain subsidiaries of Orthofix Medical Inc. as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Current Report on Form 8-K filed August 6, 2018 and incorporated herein by reference). |
| 10.5† | Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference). |

| Exhibit Number | Description |
|---|---|
| 10.6 | Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference). |
| 10.7† | Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference). |
| 10.8† | Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2013 and incorporated herein by reference). |
| 10.9 | Amendment No. 4 to Matrix Commercialization Collaboration Agreement, entered into on April 1, 2014, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed April 7, 2014 and incorporated herein by reference). |
| 10.10† | Amendment No. 5 to Matrix Commercialization Collaboration Agreement, entered into on March 10, 2016, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed March 14, 2016 and incorporated herein by reference). |
| 10.11† | Amendment No. 6 to Matrix Commercialization Collaboration Agreement, entered into on December 29, 2017, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual report on Form 10-K filed February 26, 2018 and incorporated herein by reference). |
| 10.12* | Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as Amended. |
| 10.13* | Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan. |
| 10.14 | Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Form 10-Q filed on August 7, 2017 and incorporated herein by reference). |
| 10.15 | Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference). |
| 10.16 | Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference). |
| 10.17 | |

Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (*initial grant*) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).

10.18 Form of 2016 Employee Performance Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).

10.19 Form of Employee Performance Vesting Restricted Stock and Performance Share Unit Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2015 Grants (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).

10.20 Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).

10.21 Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).

| Exhibit Number | Description |
|---|---|
| 10.22 | Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference). |
| 10.23 | Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference). |
| 10.24 | Employee Inducement Restricted Stock Unit Agreement for Beth Stevenson (filed as an exhibit to the Company's Form S-8 filed on February 2, 2019 and incorporated herein by reference). |
| 10.25 | Inducement Plan for Spinal Kinetics Employees (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference). |
| 10.26 | Form of Inducement Grant Non-Qualified Stock Option Agreement (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference). |
| 10.27 | Form of Inducement Grant Restricted Stock Agreement (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference). |
| 10.28 | Inducement Grant Non-Qualified Stock Option Agreement, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Current Report on Form 8-K filed March 13, 2013 and incorporated herein by reference). |
| 10.29 | Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference). |
| 10.30 | Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants made under the 2004 Long Term Incentive Plan prior to the adoption of the 2012 Long Term Incentive Plan) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 7, 2009 and incorporated herein by reference). |
| 10.31 | Form of Indemnification Agreement between Orthofix Medical Inc. and its directors and officers (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4 (Registration No. 333-224407) filed April 23, 2018). |
| 10.32 | Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference). |
| 10.33 | Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference). |
| 10.34 | |

| | |
|---|---|
| | Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference). |
| 10.35 | Change in Control and Severance Agreement, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed September 9, 2016 and incorporated herein by reference). |
| 10.36 | Amended and Restated Employment Contract, dated July 31, 2018 between Orthofix AG and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed August 6, 2018 and incorporated herein by reference). |
| 10.37 | Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley V. Niemann (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference). |

| Exhibit Number | Description |
|---|---|
| 10.38 | Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference). |
| 10.39* | Transition and Retirement Agreement, dated February 25, 2019, between Bradley R. Mason and Orthofix Medical Inc. |
| 21.1* | List of Subsidiaries. |
| 23.1* | Consent of Independent Registered Public Accounting Firm. |
| 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 Certification of Chief Executive Officer and Certification of Chief Financial Officer. |
| 101 | The following financial statements from Orthofix Medical Inc. on Form 10-K for the year ended December 31, 2018 filed on February 25, 2019, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income and Comprehensive Income, (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements. |

*Filed with this Form 10-K.

†Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. This exhibit has been filed separately with the Secretary of the Commission without redactions pursuant to our Application Requesting Confidential Treatment under the Securities Exchange Act of 1934.

**Item 16.** Form 10-K Summary

None

**SIGNATURES**

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

ORTHOFIX MEDICAL INC.

Dated: February 25, 2019 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer, Director

Dated: February 25, 2019 By: /s/ DOUG RICE
Name: Doug Rice
Title: Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Name | Title | Date |
|---|---|---|
| /s/ BRADLEY R. MASON | President and Chief Executive Officer, Director | February 25, 2019 |
| Bradley R. Mason | (Principal Executive Officer) | |
| /s/ DOUG RICE | Chief Financial Officer | February 25, 2019 |
| Doug Rice | (Principal Financial and Accounting Officer) | |
| /s/ RONALD A. MATRICARIA | Chairman of the Board of Directors | February 25, 2019 |
| Ronald A. Matricaria | | |
| /s/ LUKE FAULSTICK | Director | February 25, 2019 |
| Luke Faulstick | | |
| /s/ JAMES HINRICHS | Director | February 25, 2019 |
| James Hinrichs | | |
| /s/ ALEXIS V. LUKIANOV | Director | February 25, 2019 |
| Alexis V. Lukianov | | |
| /s/ LILLY MARKS | Director | February 25, 2019 |

| | | |
|---|---|---|
| Lilly Marks | | |
| /s/ MICHAEL E. PAOLUCCI<br>Michael E. Paolucci | Director | February 25, 2019 |
| /s/ MARIA SAINZ<br>Maria Sainz | Director | February 25, 2019 |
| /s/ JOHN SICARD<br>John Sicard | Director | February 25, 2019 |

**ORTHOFIX MEDICAL INC.**

Statement of Management's Responsibility for Financial Statements

To the Shareholders of Orthofix Medical Inc.:

Management is responsible for the preparation of the consolidated financial statements and related information that are presented in this Annual Report. The consolidated financial statements, which include amounts based on management's estimates and judgments, have been prepared in conformity with accounting principles generally accepted in the United States. Other financial information in the report to shareholders is consistent with that in the consolidated financial statements.

The Company maintains accounting and internal control systems to provide reasonable assurance at a reasonable cost that assets are safeguarded against loss from unauthorized use or disposition, and that the financial records are reliable for preparing financial statements and maintaining accountability for assets. These systems are augmented by written policies, an organizational structure providing division of responsibilities and careful selection and training of qualified personnel.

The Company engaged Ernst & Young LLP, independent registered public accountants, to audit and render an opinion on the consolidated financial statements in accordance with auditing standards of the Public Company Accounting Oversight Board (United States). These standards include an assessment of the systems of internal controls and test of transactions to the extent considered necessary by them to support their opinion.

The Board of Directors, through its Audit Committee consisting solely of outside directors of the Company, meets periodically with management and our independent registered public accountants to ensure that each is meeting its responsibilities and to discuss matters concerning internal controls and financial reporting. Ernst & Young LLP has full and free access to the Audit Committee.

James F. Hinrichs

Chairman of the Audit Committee

Bradley R. Mason

President and Chief Executive Officer, Director

Doug Rice

Chief Financial Officer

**ORTHOFIX MEDICAL INC.**

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Orthofix Medical Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orthofix Medical Inc. (formerly Orthofix International N.V.) (the Company) as of December 31, 2018 and 2017, the related consolidated statements of income and comprehensive income, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2019 expressed an unqualified opinion thereon.

Adoption of New Accounting Standards

As discussed in Notes 2 and 15 to the consolidated financial statements, the Company changed its methods of accounting for 1) recognition of revenue from contracts with customers in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*, 2) measurement of equity investments at fair value and the recognition of any changes in fair value in 2018 due to the adoption of ASU No. 2016-01, *Financial Instruments* and ASU 2018-03, *Technical Connections and Improvements to Financial Instruments*, 3) intra-entity transfers of assets in 2018 and 2017 due to the adoption of ASU No. 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*, and 4) classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows in 2018 and 2017 due to the adoption of ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash*.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

Dallas, Texas

February 25, 2019

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2018 and 2017

| (U.S. Dollars, in thousands except share and per share data) | 2018 | 2017 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $69,623 | $81,157 |
| Restricted cash | 2,566 | — |
| Trade accounts receivable, less allowances of $7,463 and $8,405 at December 31, 2018 and 2017, respectively | 77,747 | 63,437 |
| Inventories | 76,847 | 81,330 |
| Prepaid expenses and other current assets | 17,856 | 25,877 |
| Total current assets | 244,639 | 251,801 |
| Property, plant and equipment, net | 42,835 | 45,139 |
| Patents and other intangible assets, net | 51,897 | 10,461 |
| Goodwill | 72,401 | 53,565 |
| Deferred income taxes | 33,228 | 23,315 |
| Other long-term assets | 21,641 | 21,073 |
| Total assets | $466,641 | $405,354 |
| Liabilities and shareholders' equity | | |
| Current liabilities | | |
| Trade accounts payable | $17,989 | $18,111 |
| Other current liabilities | 67,919 | 61,295 |
| Total current liabilities | 85,908 | 79,406 |
| Other long-term liabilities | 45,336 | 29,340 |
| Total liabilities | 131,244 | 108,746 |
| Contingencies (Note 13) | | |
| Shareholders' equity | | |
| Common shares $0.10 par value; 50,000,000 shares authorized; 18,579,688 and 18,278,833 issued and outstanding as of December 31, 2018 and 2017, respectively | 1,858 | 1,828 |
| Additional paid-in capital | 243,165 | 220,591 |
| Retained earnings | 87,078 | 70,402 |
| Accumulated other comprehensive income | 3,296 | 3,787 |
| Total shareholders' equity | 335,397 | 296,608 |
| Total liabilities and shareholders' equity | $466,641 | $405,354 |

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

F-3

**ORTHOFIX MEDICAL INC.**

Consolidated Statements of Income and Comprehensive Income

For the years ended December 31, 2018, 2017 and 2016

| (U.S. Dollars, in thousands, except share and per share data) | 2018 | 2017 | 2016 |
|---|---|---|---|
| Net sales | $453,042 | $433,823 | $409,788 |
| Cost of sales | 96,628 | 93,037 | 87,853 |
| Gross profit | 356,414 | 340,786 | 321,935 |
| Sales and marketing | 205,527 | 198,370 | 181,287 |
| General and administrative | 84,506 | 71,905 | 76,409 |
| Research and development | 33,218 | 29,700 | 28,803 |
| Changes in fair value of contingent consideration | 3,069 | — | — |
| Charges related to U.S. Government resolutions (Note 13) | — | — | 14,369 |
| Operating income | 30,094 | 40,811 | 21,067 |
| Interest income (expense), net | (828) | (416) | 763 |
| Other expense, net | (6,381) | (4,004) | (2,806) |
| Income before income taxes | 22,885 | 36,391 | 19,024 |
| Income tax expense | (9,074) | (29,100) | (15,527) |
| Net income from continuing operations | 13,811 | 7,291 | 3,497 |
| Discontinued operations (Note 13) | | | |
| Loss from discontinued operations | — | (1,759) | (638) |
| Income tax benefit | — | 691 | 197 |
| Net loss from discontinued operations | — | (1,068) | (441) |
| Net income | $13,811 | $6,223 | $3,056 |
| Net income per common share—basic | | | |
| Net income from continuing operations | $0.73 | $0.40 | $0.19 |
| Net loss from discontinued operations | — | (0.06) | (0.02) |
| Net income per common share—basic | $0.73 | $0.34 | $0.17 |
| Net income per common share—diluted | | | |
| Net income from continuing operations | $0.72 | $0.39 | $0.19 |
| Net loss from discontinued operations | — | (0.05) | (0.02) |
| Net income per common share—diluted | $0.72 | $0.34 | $0.17 |
| Weighted average number of common shares: | | | |
| Basic | 18,494,002 | 18,117,405 | 18,144,019 |
| Diluted | 18,911,610 | 18,498,745 | 18,463,161 |
| | | | |
| Other comprehensive income (loss), before tax | | | |
| Unrealized gain (loss) on derivative instrument | — | — | (360) |
| Unrealized gain (loss) on debt security | 1,770 | 3,830 | (1,744) |
| Reclassification adjustment for loss on debt security in net income | — | 5,585 | 2,727 |
| Currency translation adjustment | (1,823) | 4,552 | (726) |
| Other comprehensive income (loss) before tax | (53) | 13,967 | (103) |
| Income tax expense related to items of other comprehensive income (loss) | (438) | (3,600) | (245) |
| Other comprehensive income (loss), net of tax | (491) | 10,367 | (348) |

| | | | |
|---|---|---|---|
| Comprehensive income | $13,320 | $16,590 | $2,708 |

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

**ORTHOFIX MEDICAL INC.**

Consolidated Statements of Changes in Shareholders' Equity

For the years ended December 31, 2018, 2017 and 2016

| (U.S. Dollars, in thousands, except share data) | Number of Common Shares Outstanding | Common Shares | Additional Paid-in Capital | Retained Earnings | Accumulated Other Comprehensive Income (Loss) | Total Shareholders' Equity |
|---|---|---|---|---|---|---|
| At December 31, 2015 | 18,659,696 | $ 1,866 | $ 232,126 | $ 62,551 | $ (6,232) | $ 290,311 |
| Cumulative effect adjustment from adoption of ASU 2016-09 | — | — | 2,032 | (1,428) | — | 604 |
| Net income | — | — | — | 3,056 | — | 3,056 |
| Other comprehensive loss, net of tax | — | — | — | — | (348) | (348) |
| Share-based compensation | — | — | 15,966 | — | — | 15,966 |
| Common shares issued | 713,140 | 71 | 17,242 | — | — | 17,313 |
| Retirement of repurchased common stock | (1,544,681) | (154) | (63,271) | — | — | (63,425) |
| At December 31, 2016 | 17,828,155 | $ 1,783 | $ 204,095 | $ 64,179 | $ (6,580) | $ 263,477 |
| Net income | — | — | — | 6,223 | — | 6,223 |
| Other comprehensive income, net of tax | — | — | — | — | 10,367 | 10,367 |
| Share-based compensation | — | — | 12,557 | — | — | 12,557 |
| Common shares issued | 450,678 | 45 | 3,939 | — | — | 3,984 |
| At December 31, 2017 | 18,278,833 | $ 1,828 | $ 220,591 | $ 70,402 | $ 3,787 | $ 296,608 |
| Cumulative effect adjustment from adoption of ASU 2014-09 | — | — | — | 4,761 | — | 4,761 |
| Cumulative effect adjustment from adoption of ASU 2016-16 | — | — | — | (1,896) | — | (1,896) |
| Net income | — | — | — | 13,811 | — | 13,811 |
| Other comprehensive loss, net of tax | — | — | — | — | (491) | (491) |
| Share-based compensation | — | — | 18,930 | — | — | 18,930 |
| Common shares issued | 300,855 | 30 | 3,644 | — | — | 3,674 |
| At December 31, 2018 | 18,579,688 | $ 1,858 | $ 243,165 | $ 87,078 | $ 3,296 | $ 335,397 |

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

**ORTHOFIX MEDICAL INC.**

Consolidated Statements of Cash Flows

For the years ended December 31, 2018, 2017 and 2016

| (U.S. Dollars, in thousands) | 2018 | 2017 | 2016 |
|---|---|---|---|
| Cash flows from operating activities | | | |
| Net income | $13,811 | $6,223 | $3,056 |
| Adjustments to reconcile net income to net cash from operating activities | | | |
| Depreciation and amortization | 18,659 | 20,124 | 20,841 |
| Amortization of debt costs and other assets | 1,024 | 1,712 | 1,569 |
| Provision for doubtful accounts | (599) | 1,639 | 1,117 |
| Deferred income taxes | (2,661) | 21,286 | 10,460 |
| Share-based compensation | 18,930 | 12,557 | 15,966 |
| Other-than-temporary impairment on debt securities | — | 5,585 | 2,727 |
| Loss on valuation of equity securities | | | |