Anika Therapeutics, Inc.
Form 10-Q
May 03, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

o **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 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
32 Wiggins Avenue, Bedford, Massachusetts	**01730**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: **(781) 457-9000**

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report: **N/A**

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 x No o

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

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

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes o No x

As of April 28, 2016 there were 14,330,582 outstanding shares of Common Stock, par value $.01 per share.

ANIKA THERAPEUTICS, INC.

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References in this Quarterly Report on Form 10-Q to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

ANIKA, ANIKA THERAPEUTICS, CINGAL, HYAFF, MONOVISC, and ORTHOVISC are our registered trademarks. This Quarterly Report on Form 10-Q also contains registered marks, trademarks, and trade names that are the property of other companies and licensed to us.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except share data and per share data)

(unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$92,837	$110,707
Investments	23,000	27,751
Accounts receivable, net of reserves of $174 and $167 at March 31, 2016 and December 31, 2015, respectively	14,798	21,652
Inventories	15,765	14,938
Prepaid expenses and other current assets	1,500	1,385
Total current assets	147,900	176,433
Property and equipment, net	46,839	40,108
Long-term deposits and other	69	69
Intangible assets, net	11,859	11,656
Goodwill	7,790	7,482
Total Assets	$214,457	$235,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$3,263	$8,302
Accrued expenses and other current liabilities	5,999	4,778
Income taxes payable	1,603	4,198
Total current liabilities	10,865	17,278
Other long-term liabilities	739	781
Long-term deferred revenue	63	66
Deferred tax liability	7,422	6,775
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	-	-

Common stock, $.01 par value; 30,000,000 shares authorized, 14,768,325 and 15,036,808 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	148	150
Additional paid-in-capital	58,536	81,685
Accumulated other comprehensive loss	(5,873)	(6,649)
Retained earnings	142,557	135,662
Total stockholders' equity	195,368	210,848
Total Liabilities and Stockholders' Equity	$214,457	$235,748

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Income

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2016	2015
Product revenue	$22,278	$15,515
Licensing, milestone and contract revenue	5	5
Total revenue	22,283	15,520
Operating expenses:		
Cost of product revenue	5,425	4,313
Research & development	2,159	2,098
Selling, general & administrative	3,990	3,605
Total operating expenses	11,574	10,016
Income from operations	10,709	5,504
Interest income, net	72	24
Income before income taxes	10,781	5,528
Provision for income taxes	3,886	2,012
Net income	$6,895	$3,516
Basic net income per share:		
Net income	$0.46	$0.24
Basic weighted average common shares outstanding	14,875	14,905
Diluted net income per share:		
Net income	$0.45	$0.23
Diluted weighted average common shares outstanding	15,307	15,330
Net income	$6,895	$3,516
Other comprehensive income (loss):		
Foreign currency translation adjustment	776	(2,249)
Comprehensive income	$7,671	$1,267

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended 31,	
	2016	2015
Cash flows from operating activities:		
Net income	$6,895	$3,516
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	942	914
Stock-based compensation expense	817	555
Deferred income taxes	555	(177)
Provision for inventory	82	30
Tax benefit from equity awards	(364)	(934)
Changes in operating assets and liabilities:		
Accounts receivable	7,034	761
Inventories	(787)	(284)
Prepaid expenses, other current and long-term assets	(267)	477
Prepaid income taxes	-	(1,199)
Accounts payable	(3,629)	632
Accrued expenses and other current liabilities	(1,306)	(375)
Deferred revenue	(39)	112
Income taxes payable	(2,205)	-
Other long-term liabilities	(48)	(44)
Net cash provided by operating activities	7,680	3,984
Cash flows from investing activities:		
Proceeds from maturity of investments	14,250	1,500
Purchase of investments	(9,499)	(7,250)
Purchase of property and equipment	(6,418)	(256)
Net cash used in investing activities	(1,667)	(6,006)
Cash flows from financing activities:		
Repurchases of common stock	(25,000)	-
Proceeds from exercise of equity awards	668	964
Tax benefit from equity awards	364	934
Net cash (used in) provided by financing activities	(23,968)	1,898
Exchange rate impact on cash	85	(230)
Decrease in cash and cash equivalents	(17,870)	(354)
Cash and cash equivalents at beginning of period	110,707	100,156

Cash and cash equivalents at end of period	$92,837	$99,802
Supplemental disclosure of cash flow information:		
Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$824	$24

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ANIKA THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except otherwise noted)

(**unaudited**)

1. Nature of Business

Anika Therapeutics, Inc. is a global, integrated orthopedic medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. The Company has over two decades of expertise developing, manufacturing, and commercializing more than 20 products, in markets across the globe, based on the Company's proprietary hyaluronic acid technology. The Company's orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with U.S. Food and Drug Administration ("FDA") and foreign regulations and approval requirements, as well as the ability to grow the Company's business through appropriate commercial strategies.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in accordance with accounting principles generally accepted in the United States ("US GAAP"). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. The year-end consolidated balance sheet is derived from the Company's audited financial statements, but does not include all disclosures required by US GAAP. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of March 31, 2016, the results of its operations for the three-month periods ended March 31, 2016 and 2015, and cash flows for the three-month periods ended March 31, 2016 and 2015.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company's annual financial statements filed with its Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the three-month period ended March 31, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016. Certain prior period

amounts have been reclassified to conform to the current period presentation. There was no impact on operating income.

3. Recent Accounting Pronouncements

Recently Issued

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 supersedes the revenue recognition requirements in "Topic 605, Revenue Recognition" and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In July 2015, the FASB issued a deferral of ASU 2014-09 of one year making it effective for annual reporting periods beginning on or after December 15, 2017 while also providing for early adoption not to occur before the original effective date. The Company is assessing the appropriate method for implementing ASU 2014-09, as well as the impact the adoption of ASU 2014-09 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). ASU 2016-02 amends existing leasing accounting requirements. The most significant change will result in the recognition of lease assets and lease liabilities by lessees for virtually all leases. The new guidance will also require significant additional disclosures about the amount, timing and uncertainty of cash flows from leases. ASU 2016-02 is effective for fiscal years and interim periods beginning after December 15, 2018. Upon adoption, entities are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted, and a number of optional practical expedients may be elected to simplify the impact of adoption. The Company is evaluating the impact of adopting this guidance.

In March 2016, the FASB issued ASU No. 2016-09, Compensation (Topic 718) Stock Compensation. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. Early adoption is permitted. The Company is assessing the appropriate method for implementing ASU 2016-09 and the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures.

Recently Adopted

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330) Simplifying the Measurement of Inventory. ASU 2015-11 more closely aligns the measurement of inventory in US GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The provisions of ASU 2015-11 are effective for annual and interim periods beginning after December 15, 2016. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of this amendment did not have a material impact on the Company’s financial position or results of operations.

In November 2015, FASB issued ASU No. 2015-17, Income Taxes (Topic 740) Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. The ASU simplifies the current guidance, which requires entities to separately present deferred tax assets and deferred tax liabilities as current and noncurrent in a classified balance sheet. The guidance in ASU 2015-17 is required for annual reporting periods beginning after December 15, 2016, including interim periods within the reporting period. The Company early adopted the provisions of this ASU during the fourth quarter of year 2015 and applied it retrospectively. The adoption of ASU 2015-17 resulted in the reclassification of $1.8 million and $2.3 million of current deferred tax assets to a reduction in noncurrent deferred tax liabilities as of March 31, 2016 and December 31, 2015, respectively. Adoption of this standard did not impact results of operations, retained earnings, or cash flows in the current or previous interim and annual reporting periods.

4. Investments

All of the Company’s investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income, net of related income taxes. The Company held bank certificates of deposit of $23.0 million and $25.8 million at March 31, 2016 and December 31, 2015, respectively. The Company also held corporate debt securities of $2.0 million at December 31, 2015. There were no unrealized gains or losses on the Company’s available-for-sale securities at March 31, 2016 or December 31, 2015.

5. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability. As a basis for classifying the fair value measurements, a three-tier fair value hierarchy, which classifies the fair value measurements based on the inputs used in measuring fair value, was established as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets or liabilities; (Level 2) significant other observable inputs that are observable either directly or indirectly; and (Level 3) significant unobservable inputs for which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, the Company records its investments at fair value.

The Company’s investments are all classified within Level 2 of the fair value hierarchy. These investments classified within Level 2 of the fair value hierarchy are valued based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk.

The fair value hierarchy of the Company's cash equivalents and investments at fair value is as follows:

	March 31, 2016	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 66,449	$ -	$ 66,449	$ -
Investments:				
Bank certificates of deposit	$ 23,000	-	$ 23,000	-

	December 31, 2015	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 61,385	$ -	$ 61,385	$ -
Bank certificates of deposit	250	-	250	-
Total cash equivalents	$ 61,635	$ -	$ 61,635	$ -
Investments:				
Corporate debt securities	$ 2,001	$ -	$ 2,001	$ -
Bank certificates of deposit	25,750	-	25,750	-
Total investments	$ 27,751	$ -	$ 27,751	$ -

6. Equity Incentive Plan

The Company estimates the fair value of stock options and stock appreciation rights ("SARs") using the Black-Scholes valuation model. Fair value of restricted stock awards ("RSAs") and restricted stock units ("RSUs") are measured by the grant-date price of the Company's shares. The fair value of each stock option award during the three-month periods ended March 31, 2016 and 2015, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	2015
Risk free interest rate	1.16% - 1.40%	1.15 %
Expected volatility	50.84% - 51.61%	54.65 %
Expected life (years)	4.5	4.5
Expected dividend yield	0.00%	0.00 %

The Company recorded $0.8 million and $0.6 million of share-based compensation expense for the three-month periods ended March 31, 2016 and 2015, respectively, for equity compensation awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the respective recipients.

During the three-month period ended March 31, 2016, the Company granted under the Plan a total of 288,705 stock options, 46,300 RSAs, and 11,805 RSUs. All of the RSUs were granted to directors of the Company and vest over a one year period. The stock options, and RSAs granted to employees generally become exercisable or vest ratably over four years from the date of grant.

A portion of the stock options granted during the three-month period ended March 31, 2016 contained certain performance features, as compared to established targets, in addition to time-based vesting conditions. For performance-based awards with financial achievement targets, the Company recognizes expense using the graded vesting methodology based on the number of shares expected to vest. Compensation cost associated with performance grants is estimated using the Black-Scholes valuation method multiplied by the expected number of shares to be issued, which is adjusted based on the estimated probabilities of achieving the performance goals. Changes to the probability assessment and the estimated shares expected to vest will result in adjustments to the related share-based compensation expense that will be recorded in the period of the change. If the performance targets are not achieved, no compensation cost is recognized and any previously recognized compensation cost is reversed.

7. Earnings Per Share (“EPS”)

Basic EPS is calculated by dividing net income by the weighted average number of shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic earnings per share. Diluted EPS is calculated by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, SARs, RSAs, and RSUs using the treasury stock method.

The following table provides share information used in the calculation of the Company's basic and diluted earnings per share:

	Three Months Ended March 31,	
	2016	2015
Shares used in the calculation of basic earnings per share	14,875	14,905
Effect of dilutive securities:		
Stock options, SARs, and RSAs	432	425
Diluted shares used in the calculation of earnings per share	15,307	15,330

Equity awards of 0.3 million and 0.1 million shares were outstanding for the three-month periods ended March 31, 2016 and 2015, respectively, and were not included in the computation of diluted earnings per share because the awards’ impact on earnings per share was anti-dilutive.

On February 26, 2016, the Company entered into an accelerated stock repurchase agreement with Morgan Stanley & Co. LLC (“Morgan Stanley”) pursuant to a Fixed Dollar Accelerated Share Repurchase Transaction (“ASR Agreement") to purchase $25.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company paid Morgan Stanley $25.0 million in cash and received an initial delivery of 377,155 shares of the Company’s common stock on February 29, 2016 based on a closing market price of $46.40 and the applicable contractual discount. This is approximately 70% of the total number of shares of expected to be repurchased under the ASR Agreement. These shares are held by the Company as authorized but unissued shares pursuant to Massachuetts law.

The initial delivery of shares resulted in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share on the effective date of the ASR Agreement.

As of March 31, 2016, the Company has approximately $7.5 million remaining under the ASR Agreement which was recorded as an equity forward sale contract and was included in additional paid-in capital in stockholders' equity in the condensed consolidated balance sheet as it met the criteria for equity accounting. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price will be determined at the end of the applicable purchase period, which is expected to occur in the third quarter of 2016. Upon settlement of the ASR Agreement, the Company may receive additional shares or be required to either pay additional cash or deliver shares of our common stock (at its option) to Morgan Stanley, based on the forward price. If the ASR Agreement had been settled as of March 31, 2016, based on the volume-weighted average price since the effective date of the ASR Agreement, Morgan Stanley would have been required to deliver approximately 0.2 million additional shares to the Company. However, the Company cannot predict the final number of shares to be received, or delivered, by it under the ASR Agreement, and, as such, these shares are not included in the calculation of diluted weighted-average common shares outstanding during the period because the effect is anti-dilutive.

8. Inventories

Inventories consist of the following:

	March 31, 2016	December 31, 2015
Raw materials	$6,059	$5,780
Work-in-process	5,647	5,656
Finished goods	4,059	3,502
Total	$15,765	$14,938

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit.

9. Intangible Assets

In connection with the 2009 acquisition of Anika Therapeutics S.r.l. ("Anika S.r.l."), the Company acquired various intangible assets and goodwill. The Company evaluated the various intangible assets and related cash flows from these intangible assets, as well as the useful lives and amortization methods related to these intangible assets. The in-process research and development ("IPR&D") intangible assets initially have indefinite lives and are reviewed periodically to assess the project status, valuation, and disposition, including write-off(s) for abandoned projects. Until such determination is made, they are not amortized.

Intangible assets as of March 31, 2016 and December 31, 2015 consist of the following:

	March 31, 2016				December 31, 2015	
	Gross Value	Accumulated Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	$17,100	$(2,882)	$ (6,148)	$8,070	$7,959	15
In-process research & development	4,406	(1,193)	-	3,213	3,099	Indefinite
Distributor relationships	4,700	(415)	(4,285)	-	-	5
Patents	1,000	(173)	(345)	482	473	16
Elevess trade name	1,000	-	(906)	94	125	9
Total	$28,206	$(4,663)	$ (11,684)	$11,859	$11,656	

The aggregate amortization expense related to intangible assets was $0.3 million for the three-month periods ended March 31, 2016 and 2015, respectively.

10. Goodwill

Through March 31, 2016, there have not been any events or changes in circumstances that indicate that the carrying value of goodwill may not be recoverable. Changes in the carrying value of goodwill were as follows (in thousands):

	Three Months Ended March 31, 2016	Twelve Months Ended December 31, 2015
Balance, beginning	$ 7,482	$ 8,339
Effect of foreign currency adjustments	308	(857)
Balance, ending	$ 7,790	$ 7,482

11. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2016	December 31, 2015
Compensation and related expenses	$2,072	$ 3,082
Facility construction costs	2,069	415
Research grants	397	381
Professional fees	372	210
Clinical trial costs	123	252
Other	966	438
Total	$5,999	$ 4,778

12. Commitments and Contingencies

In certain of its contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate, or breach any U.S. patent or intellectual property right, trade secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligent acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes the estimated fair value of these indemnification agreements is immaterial. The Company has no accrued warranties at March 31, 2016 or December 31, 2015, respectively, and has no history of claims paid.

The Company is also involved in various legal proceedings arising in the normal course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, the Company does not expect the resolution of these legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flow.

13. Leases

On October 9, 2015, Anika S.r.l. entered into a build-to-suit lease agreement with Consorzio Zona Industriale E Porto Fluviale di Padova ("ZIP"), as landlord, pursuant to which Anika S.r.l. will lease a new European headquarters facility, consisting of approximately 33,000 square feet of general office, research and development, training, and warehousing space located in Padova, Italy. The lease has an initial term of fifteen years, which is expected to commence during the fourth quarter of 2016 once construction of the facility is completed. The lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The Company has the ability to withdraw from this lease subject to certain financial penalties after six years and with no penalties after the ninth year. Beginning on the commencement date, the lease provides for an initial yearly rent of approximately $0.4 million.

Construction of the new facility began in the first quarter of 2016 and is expected to be completed in late 2016. During the period of construction the Company is considered the deemed owner of the facility. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in the Company's consolidated balance sheet. As of March 31, 2016, the Company has recorded a construction-in-process asset of approximately $0.3 million. This included $0.1 million incurred by ZIP for the construction of the new facility, which was recorded as a facility lease obligation on the balance sheet.

14. Income Taxes

Provisions for income taxes were $3.9 million and $2.0 million for the three-month periods ended March 31, 2016 and 2015, respectively, based on effective tax rates of 36.1% and 36.4%. The increase in income taxes for the three-month

period ended March 31, 2016 resulted from higher net income as compared to the same period last year. The net decrease in the effective tax rate for the three-month period ended March 31, 2016, as compared to the same period in 2015, was primarily due to an increase in the expected tax credit for research and development expenditures.

The Company files income tax returns in the United States on a federal basis, in certain U.S. states, and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. The Company's filings from 2012 through the present tax year remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The Company's filings from 2011 through the present tax year remain subject to examination by the appropriate governmental authorities in Italy.

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its net operating loss carryforward. The Company concluded that the positive evidence outweighs the negative evidence and, thus, those deferred tax assets are realizable on a "more likely than not" basis. As such, the Company did not record a valuation allowance at March 31, 2016 or December 31, 2015.

15. Segment and Geographic Information

The Company has one reportable operating segment, for the purposes of assessing performance and deciding how to allocate resources.

Product revenue by product group is as follows:

	Three Months Ended March 31,	
	2016	2015
Orthobiologics	$19,587	$11,973
Surgical	1,318	1,390
Dermal	381	416
Other	992	1,736
Product Revenue	$22,278	$15,515

Total revenue by geographic location and as a percentage of overall total revenue for the three-month periods ended March 31, 2016 and 2015 are as follows:

	Three Months Ended March 31,					
	2016			2015		
	Total Revenue	Percentage of Revenue		Total Revenue	Percentage of Revenue	
Geographic Location:						
United States	$18,011	81	%	$12,591	81	%
Europe	2,565	11	%	1,986	13	%
Other	1,707	8	%	943	6	%
Total Revenue	$22,283	100	%	$15,520	100	%

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with our financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties, and assumptions that could cause our actual results to differ materially from our expectations. Words such as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "future," "can," "could," and other expressions that are predictions of or indicate future events and trends and which do not relate to historical matters are intended to identify such forward-looking statements. These statements are likely to relate to, among other things, our goals, plans and projections regarding our financial position, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance, and results related to current or anticipated products. You should carefully consider forward-looking statements and understand that such statements may be affected by inaccurate assumptions and may involve a variety of risks and uncertainties, known and unknown, including, among others, risks related to competition in the medical device industry, reduction or interruption in our supply, quality problems, decreasing prices, changes in applicable tax rates, adverse regulatory action, health care policy changes, international operations, or disruption of our current plans and operations, as well as those factors described in Part II, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015, and as may be updated in our subsequent Quarterly Reports on Form 10-Q. Consequently, no forward-looking statements can be guaranteed and actual results may vary materially, and you should take caution not to place undue reliance on such statements. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events, or otherwise.

Management Overview

We are a global, integrated orthopedic medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. We have over two decades of expertise developing, manufacturing, and commercializing our products, in markets across the globe, based on our proprietary hyaluronic acid ("HA") technology. Our orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration.

Our therapeutic offerings consist of products in the following areas: Orthobiologics, Dermal, Surgical, Ophthalmic, and Veterinary. All of our products are based on HA, a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies HA to allow for longer residence time in the body. We also offer products made from HA based on two other technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Our technologies are protected by an extensive portfolio of owned and licensed patents.

Since our inception in 1992, we have utilized a commercial partnership model for the distribution of our products to end-users. Our strong, worldwide network of distributors has historically provided, and continues to provide, a solid foundation for our revenue growth and territorial expansion. In 2015, we made the strategic decision to commercialize our next generation viscosupplementation product, CINGAL, in the United States ourselves, initially through the engagement of a contract sales organization. Ultimately, we intend to transition the direct sales function into our company as part of a broader buildout of our commercial capabilities. We believe that the combination of the direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio.

We began a strategic project in 2015 to move the manufacturing of our HYAFF-based products, which currently are manufactured by a third party in Italy, to our Bedford, Massachusetts facility. Our main purposes behind this strategic move are to improve the efficiency of our manufacturing process and to enhance our research and development capabilities, with the aim of accelerating future product development. We expect to expend approximately $15 million on this project through 2018.

Please see the section captioned “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations-Management Overview” in our Annual Report on Form 10-K for the year ended December 31, 2015, for a description of each of the above therapeutic areas, including the individual products.

Research and Development

Our research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities for our existing and new products. Our development focus includes products for tissue protection, repair, and regeneration. We anticipate that we will continue to commit significant resources to research and development, including in relation to clinical trials, in the future.

Our second single-injection osteoarthritis product under development is CINGAL, which is composed of our proprietary cross-linked HA material combined with an approved steroid and is designed to provide both short- and long-term pain relief to patients. We completed the CINGAL phase III clinical trial and associated statistical analysis during the fourth quarter of 2014. During the first half of 2015, we completed a CINGAL retreatment study with patients who had participated in the phase III clinical trial and reported safety data related to the retreatment study. We announced notification of approval for CINGAL from Health Canada in November 2015 for the treatment of pain in osteoarthritis of the knee. In March 2016, we received CE Mark approval of CINGAL as a viscoelastic supplement or as a replacement for synovial fluid in human joints. We expect the first commercial sale of CINGAL in both Canada and the European Union to occur in the second quarter of 2016. After discussions with the FDA related to the regulatory pathway for CINGAL, we conducted a formal meeting with the FDA's Office of Combination Products ("OCP") to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to the FDA's Center for Drug Evaluation and Research ("CDER") as the lead agency center for premarket review and regulation. Since then, we have been in ongoing discussions with CDER to understand the requirements for submitting an NDA for CINGAL, and preliminary indications from CDER suggest that additional clinical work may be required. We will meet with the FDA to collaboratively discuss this topic.

We have several research and development programs underway for new products, including for HYALOFAST (in the United States), an innovative product for cartilage tissue repair, HYALOBONE, a bone void filler, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption for HYALOFAST to the FDA, which was approved in July 2015. We commenced patient enrollment in December 2015, and we are in the early stages of the phase III clinical trial for HYALOFAST. We are also currently proceeding with two other research and development programs. The first focuses on the potential of utilizing our proprietary HA technology to treat pain associated with common repetitive overuse injuries, such as those to the elbow, rotator cuff and Achilles tendon. We submitted a CE mark application for this treatment during the first quarter of 2016, and we are currently evaluating the requirements for a submission to the FDA. The second program is in the early pre-clinical stage, and it explores the possibility of using our HYAFF technology in synthetic bone grafts to repair and reconstruct hips, extremities, and the spine.

In June 2015, we entered into an agreement with the Institute for Applied Life Sciences at the University of Massachusetts Amherst to collaborate on research to develop a therapy for rheumatoid arthritis. The purpose of this research is to develop a novel modality for the treatment of rheumatoid arthritis, and if successful, it is expected to

yield a potential product candidate that we could begin to move towards commercialization as early as 2017.

Results of Operations

Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015

	Three Months Ended March 31,				
	2016	2015	$ Inc/(Dec)	% Inc/(Dec)	
	(in thousands, except percentages)				
Product revenue	$22,278	$15,515	$ 6,763	44	%
Licensing, milestone and contract revenue	5	5	-	0	%
Total revenue	22,283	15,520	6,763	44	%
Operating expenses:					
Cost of product revenue	5,425	4,313	1,112	26	%
Research & development	2,159	2,098	61	3	%
Selling, general & administrative	3,990	3,605	385	11	%
Total operating expenses	11,574	10,016	1,558	16	%
Income from operations	10,709	5,504	5,205	95	%
Interest income, net	72	24	48	200	%
Income before income taxes	10,781	5,528	5,253	95	%
Provision for income taxes	3,886	2,012	1,874	93	%
Net income	$6,895	$3,516	$ 3,379	96	%
Product gross profit	$16,853	$11,202	$ 5,651	50	%
Product gross margin	76%	72%			

Product Revenue

Product revenue for the quarter ended March 31, 2016 was $22.3 million, an increase of 44% as compared to $15.5 million for the quarter ended March 31, 2015. For the three months ended March 31, 2016, the increase in product revenue was driven by our orthobiologics franchise, which was partially offset by decreases in our dermal and other product revenue as a result of the timing of orders for our ophthalmic and veterinary products.

The following tables present product revenue by group for the three-month periods ended March 31, 2016 and 2015:

Three Months Ended March 31,			
2016	2015	$ Inc/(Dec)	% Inc/(Dec)
(in thousands, except percentages)			

Orthobiologics	$19,587	$11,973	$ 7,614	64 %
Surgical	1,318	1,390	(72)	(5 %)
Dermal	381	416	(35)	(8 %)
Other	992	1,736	(744)	(43 %)
Total	$22,278	$15,515	$ 6,763	44 %

Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 64% for the three months ended March 31, 2016, as compared to the same period in 2015. The growth in the first quarter of 2016 reflected a significant increase in product purchases as compared with the same period in the prior year during which our U.S. commercial partner implemented a multi-month inventory reset program. Product sales to our U.S. commericial partner increased by approximately $5.8 million as compared to the first quarter of 2015. More importantly, we also experienced growing end-user demand during the first quarter of 2016, resulting in increased revenue from worldwide ORTHOVISC and worldwide MONOVISC sales. We expect orthobiologics revenue to continue to grow in 2016, led by increased MONOVISC revenue in the United States, the expected commercial launch of CINGAL in Canada and Europe, as well as overall revenue growth from our viscosupplementation products both domestically and internationally.

Surgical

Our surgical franchise consists of products used to prevent surgical adhesions and to treat ear, nose, and throat, or ENT, disorders. Sales of our surgical products decreased 5% for the three-month period ended March 31, 2016 to $1.3 million, as compared to the same period in 2015. The decrease in surgical product revenue for the three-month period was primarily due to the unfavorable impact from foreign currency exchange rate fluctuations as compared with the same period in the prior year. We expect surgical product revenue to decrease moderately for the full-year 2016 compared to 2015