

Anika Therapeutics, Inc.
Form 10-Q
May 04, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2015

☐ 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
(State or Other Jurisdiction of
Incorporation or Organization)

04-3145961
(I.R.S. Employer Identification No.)

32 Wiggins Avenue, Bedford, Massachusetts
(Address of Principal Executive Offices)

01730
(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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

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 <input type="radio"/>	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="radio"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="radio"/>
--	---	---	--

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

As of April 30, 2015 there were 14,626,730 outstanding shares of Common Stock, par value \$.01 per share.

ANIKA THERAPEUTICS, INC.
TABLE OF CONTENTS

	Page
Part I	
<u>Item 1.</u>	<u>Financial Statements (unaudited):</u> <u>2</u>
	<u>Condensed consolidated Balance Sheets as of March 31, 2015 and</u> <u>2</u>
	<u>December 31, 2014</u>
	<u>Condensed consolidated Statements of Operations and Comprehensive</u> <u>3</u>
	<u>Income for the three months ended March 31, 2015 and 2014</u>
	<u>Condensed consolidated Statements of Cash Flows for the three months</u> <u>4</u>
	<u>ended March 31, 2015 and 2014</u>
	<u>Notes to condensed consolidated financial statements</u> <u>5</u>
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results</u> <u>11</u>
	<u>of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> <u>16</u>
<u>Item 4.</u>	<u>Controls and Procedures</u> <u>16</u>
Part II	
<u>Item 1.</u>	<u>Legal Proceedings</u> <u>16</u>
<u>Item 1A.</u>	<u>Risk Factors</u> <u>17</u>
<u>Item 6.</u>	<u>Exhibits</u> <u>17</u>
<u>Signatures</u>	<u>18</u>

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, HYVISC, 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.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

ASSETS	March 31, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	\$ 99,802,205	\$ 100,155,864
Investments	12,500,000	6,750,000
Accounts receivable, net of reserves of \$130,877 and \$146,618 at March 31, 2015 and December 31, 2014, respectively	16,025,212	17,152,028
Inventories	12,515,787	12,406,776
Prepaid income taxes	2,555,436	412,301
Current portion deferred income taxes	1,487,846	1,188,768
Prepaid expenses and other	1,034,597	959,305
Total current assets	145,921,083	139,025,042
Property and equipment, at cost	53,666,109	53,619,589
Less: accumulated depreciation	(22,476,104)	(21,950,706)
	31,190,005	31,668,883
Long-term deposits and other	69,010	69,042
Intangible assets, net	13,061,379	14,894,710
Goodwill	7,443,429	8,338,699
Total assets	\$ 197,684,906	\$ 193,996,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,774,812	\$ 1,201,226
Accrued expenses	4,242,979	4,747,526
Deferred revenue	139,535	24,510
Total current liabilities	6,157,326	5,973,262
Other long-term liabilities	829,302	893,935
Long-term deferred revenue	85,510	102,192
Deferred tax liability	8,797,200	8,929,890
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 15,003,069 and 14,851,703 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	150,030	148,517
Additional paid-in-capital	79,990,228	77,539,699
Accumulated other comprehensive loss	(6,743,928)	(4,494,800)
Retained earnings	108,419,238	104,903,681
Total stockholders' equity	181,815,568	178,097,097
Total Liabilities and Stockholders' Equity	\$ 197,684,906	\$ 193,996,376

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

ITEM 1. FINANCIAL STATEMENTS
Anika Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income
(unaudited)

	Three Months Ended March 31,	
	2015	2014
Product revenue	\$ 15,514,682	\$ 14,351,405
Licensing, milestone and contract revenue	5,642	19,658,882
Total revenue	15,520,324	34,010,287
Operating expenses:		
Cost of product revenue	4,313,440	4,361,019
Research & development	2,097,762	2,287,715
Selling, general & administrative	3,604,661	3,490,985
Total operating expenses	10,015,863	10,139,719
Income from operations	5,504,461	23,870,568
Interest income, net	23,723	467
Income before income taxes	5,528,184	23,871,035
Provision for income taxes	2,012,627	8,840,782
Net income	\$ 3,515,557	\$ 15,030,253
Basic net income per share:		
Net income	\$ 0.24	\$ 1.04
Basic weighted average common shares outstanding	14,905,322	14,461,367
Diluted net income per share:		
Net income	\$ 0.23	\$ 0.97
Diluted weighted average common shares outstanding	15,330,054	15,499,447
Net income	\$ 3,515,557	\$ 15,030,253
Other comprehensive income:		
Foreign currency translation adjustment	(2,249,128)	(26,116)
Comprehensive income	\$ 1,266,429	\$ 15,004,137

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
(unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net income	\$ 3,515,557	\$ 15,030,253
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	913,859	1,198,799
Stock-based compensation expense	554,597	427,823
Deferred income taxes	(177,123)	(323,669)
Provision for inventory	29,922	31,778
Tax benefit from exercise of stock options	(933,863)	(4,436,249)
Changes in operating assets and liabilities:		
Accounts receivable	761,041	2,140,848
Inventories	(284,016)	(2,016,631)
Prepaid expenses, other current and long-term assets	476,935	(345,415)
Prepaid income taxes	(1,198,483)	-
Accounts payable	632,521	51,712
Accrued expenses	(374,682)	(1,104,945)
Deferred revenue	111,697	(2,113,086)
Income taxes payable	-	5,099,027
Other long-term liabilities	(44,128)	(43,588)
Net cash provided by operating activities	3,983,834	13,596,657
Cash flows from investing activities:		
Proceeds from maturity of investments	1,500,000	-
Purchase of investments	(7,250,000)	-
Purchase of property and equipment	(256,020)	(276,513)
Net cash used in investing activities	(6,006,020)	(276,513)
Cash flows from financing activities:		
Proceeds from exercise of stock options	963,582	1,067,767
Tax benefit from exercise of stock options	933,863	4,436,249
Net cash provided by financing activities	1,897,445	5,504,016
Exchange rate impact on cash	(228,918)	2,931
(Decrease) increase in cash and cash equivalents	(353,659)	18,827,091
Cash and cash equivalents at beginning of period	100,155,864	63,333,160
Cash and cash equivalents at end of period	\$ 99,802,205	\$ 82,160,251

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

ANIKA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business

Anika Therapeutics, Inc. develops, manufactures, and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (“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.

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.

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, 2015, the results of its operations for the three month periods ended March 31, 2015 and 2014, and cash flows for the three month periods ended March 31, 2015 and 2014.

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, 2014. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015. Certain prior period amounts have been reclassified to conform to the current period presentation. There was no impact on operating income.

3. 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’s investments at March 31, 2015 and December 31, 2014 are as follows:

		March 31, 2015		
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Bank certificates of deposit	\$ 12,500,000	\$ -	\$ -	\$ 12,500,000

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

		December 31, 2014		
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Bank certificates of deposit	\$6,750,000	\$ -	\$ -	\$6,750,000

5

4. 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:

Fair Value Measurements at Reporting Date Using				
	March 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash & cash equivalents:				
Money market funds	\$64,321,194	\$ -	\$ 64,321,194	\$ -
Bank certificates of deposit	2,500,000	-	2,500,000	-
Total cash & cash equivalents	\$66,821,194	\$ -	\$ 66,821,194	\$ -
Investments:				
Bank certificates of deposit	\$12,500,000	\$ -	\$ 12,500,000	\$ -

Fair Value Measurements at Reporting Date Using				
	December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash & cash equivalents:				
Money market funds	\$69,551,754	\$ -	\$ 69,551,754	\$ -
Bank certificates of deposit	3,000,000	-	3,000,000	-
Total cash & cash equivalents	\$72,551,754	\$ -	\$ 72,551,754	\$ -
Investments:				
Bank certificates of deposit	\$6,750,000	\$ -	\$ 6,750,000	\$ -

5. Equity Incentive Plan

The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Fair value of restricted stock is 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, 2015 and 2014, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,			
	2015		2014	
Risk free interest rate	1.15	%	1.20%	- 1.33%
Expected volatility	54.65	%	53.28%	
Expected life (years)	4.5		4	
Expected dividend yield	0.00	%	0.00%	

The Company recorded \$554,597 and \$427,823 of share-based compensation expense for the three-month periods ended March 31, 2015 and 2014, 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.

There were 104,125 stock options granted under the Anika Therapeutics, Inc. Second Amended and Restated Stock Option and Incentive Plan, as amended, (the "Plan") during the three month period ended March 31, 2015. There were 23,375 Restricted Stock Awards ("RSAs") granted under the Plan during the three-month period ended March 31, 2015. There were 9,678 RSUs granted to non-employee members of the Company's Board of Directors under the Plan during the three month period ended March 31, 2015. The stock options, RSAs and RSUs granted to employees and directors 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, 2015 contained certain performance features, as compared to established targets, in addition to time-based vesting conditions. The compensation cost associated with these grants was estimated using the Black-Scholes valuation method factored for the estimated probability of achieving the performance goals.

As of March 31, 2015, there was approximately \$4.9 million of total unrecognized compensation cost related to non-vested stock options, stock appreciation rights ("SARs"), RSAs, and RSUs granted under the Company's incentive plans. This cost is expected to be recognized over a weighted-average period of 3.1 years.

The total intrinsic value of stock options and SARs exercised during the three month periods ended March 31, 2015 and 2014 was \$2,975,681 and \$7,131,972, respectively. Cash received from the exercise of stock options during the three month periods ended March 31, 2015 and 2014 was \$963,582 and \$1,067,767, respectively.

There were 785,082 options and SARs outstanding under the Company's incentive plans as of March 31, 2015 with a weighted-average exercise price of \$18.64 per share, an aggregate intrinsic value of approximately \$17.7 million, and a weighted-average remaining contractual term of 7.4 years. None of the options or SARs outstanding at March 31, 2015 or 2014, respectively, had cash-settlement features.

The Company may satisfy the awards upon exercise, or upon fulfillment of the vesting requirements for other equity-based awards, with either authorized but unissued shares or shares reacquired by the Company. Stock-based awards are granted with an exercise price equal to the market price of the Company's stock on the date of grant. Awards containing service conditions generally become exercisable ratably over one to four years, have a ten year contractual term, and sometimes contain performance conditions.

6. 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, stock appreciation rights (“SAR’s”), restricted shares, and restricted stock units 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,	
	2015	2014
Shares used in the calculation of basic earnings per share	14,905,322	14,461,367
Effect of dilutive securities:		
Stock options, SARs, and RSAs	424,732	1,038,080
Diluted shares used in the calculation of earnings per share	15,330,054	15,499,447

Equity awards of 133,377 and 87,126 shares were outstanding for the three month periods ended March 31, 2015 and March 31, 2014, respectively, and were not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive.

7. Inventories

Inventories consist of the following:

	March 31, 2015	December 31, 2014
Raw materials	\$ 6,470,239	\$ 6,161,363
Work-in-process	2,911,794	3,041,227
Finished goods	3,133,754	3,204,186
Total	\$ 12,515,787	\$ 12,406,776

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.

8. Intangible Assets and Goodwill

In connection with the 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.

The Company reviews its long-lived assets for impairment at least annually on November 30. Additionally, the Company will initiate a review for impairment if events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of the assets are no longer appropriate. Each impairment test will be based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value.

In January 2015 the Company received CE Mark approval for HYALOSPINE, an adhesion prevention gel for use after spinal surgery. As a result of this approval the Company has reclassified \$400,000 from IPR&D to developed technology and began amortization on the HYALOSPINE asset.

Intangible assets as of March 31, 2015 and December 31, 2014 consist of the following:

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

	March 31, 2015				December 31, 2014		
			Currency				
	Gross Value	Completed Projects	Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$16,700,000	\$400,000	\$(3,252,179)	\$(5,260,974)	\$8,586,847	\$9,409,937	15
In-process research & development	5,502,686	(400,000)	(1,354,684)	-	3,748,002	4,652,874	Indefinite
Distributor Relationships	4,700,000	-	(415,344)	(4,284,656)	-	-	5
Patents	1,000,000	-	(196,045)	(296,787)	507,168	581,199	16
Eleves trade name	1,000,000	-	-	(780,638)	219,362	250,700	9
Total	\$28,902,686	\$-	\$(5,218,252)	\$(10,623,055)	\$13,061,379	\$14,894,710	

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

The aggregate amortization expense related to intangible assets was \$270,272 and \$538,335 for the three-month periods ended March 31, 2015 and 2014, respectively.

Changes in the carrying value of goodwill for the periods ended March 31, 2015 and December 31, 2014 were as follows:

	Three Months Ended March 31, 2015	Twelve Months Months Ended December 31, 2014
Goodwill		
Balance, beginning	\$ 8,338,699	\$ 9,443,894
Effect of foreign currency adjustments	(895,270)	(1,105,195)
Balance, ending	\$ 7,443,429	\$ 8,338,699

9. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2015	December 31, 2014
Compensation and related expenses	\$ 2,157,864	\$ 2,791,935
Professional fees	596,018	553,630
Clinical trial costs	562,072	508,042
Research grants	481,179	539,053
Other	445,846	354,866
Total	\$ 4,242,979	\$ 4,747,526

10. 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, 2015 or December 31, 2014, respectively, and has no history of claims paid.

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

11. Mitek Monovisc Agreement

In December 2011, the Company entered into a fifteen-year licensing agreement (the "Mitek MONOVISC Agreement") with DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc., to exclusively market

MONOVISC in the United States. The Company received an upfront payment of \$2,500,000 in December 2011. This non-refundable upfront payment did not have standalone value without the Company's completion of development obligations, which included obtaining regulatory approval of the product and resolving the related patent litigation. As a result, the Company recognized the upfront payment over the development obligation period. During the first quarter of 2014, the Company received FDA approval of MONOVISC and resolved the patent litigation with Genzyme Corporation. As a result of the full delivery of its development obligations under this agreement, the Company recognized approximately \$2,200,000, which represented the remaining balance of deferred revenue relating to the initial \$2,500,000 payment, in accordance with current generally accepted principles on revenue recognition. In the first quarter of 2014, the Company also received a milestone payment of \$17,500,000 as a result of achieving FDA approval for MONOVISC and resolving the patent litigation with Genzyme. This milestone payment was fully recognized as revenue during the three months ended March 31, 2014. On April 15, 2014 the first U.S. commercial sale of MONOVISC was made by the Company's commercial partner, Mitek. Under the terms of the Mitek MONOVISC Agreement, the Company earned and collected a milestone payment of \$5,000,000, which was fully recognized as revenue in the second quarter of 2014. On November 10, 2014, the Center for Medicare & Medicaid Services ("CMS") assigned a unique Healthcare Common Procedure Coding System code, or J-Code, to MONOVISC. The issuance of this J-Code by CMS allowed for the fixing of national Medicare reimbursement rates for the product. The new J-Code became effective on January 1, 2015. As a result of CMS assigning the J-Code, the Company collected a milestone payment of \$5,000,000, which was fully recognized as revenue in the fourth quarter of 2014. For the year ended December 31, 2014, the Company recognized a total of \$29,652,778 in milestone revenue related to MONOVISC.

12. Income Taxes

Provisions for income taxes were \$2,012,627 and \$8,840,782 for the three month periods ended March 31, 2015 and 2014, respectively, based on effective tax rates of 36.4% and 37.0%. The decrease in income taxes over the three month period ended March 31, 2014 was primarily due to decreased net income as a result of the approximately \$19.7 million in milestone and contract revenue recognized for the three months ended March 31, 2014 associated with the Mitek MONOVISC Agreement. See the previous discussion under Note 11. The decrease in the effective tax rate over the three month period ended March 31, 2014 was primarily due to an increase in the expected tax benefit of the domestic production deduction.

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 2011 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 2010 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, 2015 or December 31, 2014.

13. 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,	
	2015	2014
Orthobiologics	\$ 11,972,500	\$ 11,572,150
Dermal	416,183	188,651
Surgical	1,389,595	1,752,020
Ophthalmic	504,472	208,584
Veterinary	1,231,932	630,000
	\$ 15,514,682	\$ 14,351,405

Total revenue by geographic location and as a percentage of overall total revenue, for the three month periods ended March 31, 2015 and 2014 are as follows;

	Three Months Ended March 31,					
	2015			2014		
	Total Revenue	Percentage of Revenue		Total Revenue	Percentage of Revenue	
Geographic Location:						
United States	\$ 12,591,189	81	%	\$ 31,533,817	93	%
Europe	1,986,324	13	%	1,695,816	5	%
Other	942,811	6	%	780,654	2	%

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

Total	\$ 15,520,324	100	%	\$ 34,010,287	100	%
-------	---------------	-----	---	---------------	-----	---

10

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 the Section captioned “Part II, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended Dec. 31, 2014 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 develop, manufacture, and commercialize therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (“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 wholly-owned subsidiary, Anika S.r.l., has over 20 products currently commercialized, primarily in Europe. These products are also all made from HA, based on two technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Both technologies are protected by an extensive portfolio of owned and licensed patents.

Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies the HA to allow for longer residence time in the body. We offer therapeutic products from these aforementioned technologies in the following areas:

	Anika	Anika S.r.l.
Orthobiologics	X	X
Dermal		
Advanced wound care		X
Aesthetic dermatology	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care (“ENT”)		X
Ophthalmic	X	

Veterinary

X

11

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, 2014, 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, including CINGAL and HYALOFAST, 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 related to our existing and new products. Our development focus includes products for tissue protection, healing, and repair. Our investment in research and development has been important over the years, and it has varied considerably depending on the number, size, and timing of clinical trials and studies underway. We anticipate that we will continue to commit significant resources to research and development, including in relation to clinical trials, in the future.

With the acquisition of Anika S.r.l., we enhanced our research and development capabilities, our technology base, and our pipeline of product candidates. Anika S.r.l. has research and development programs underway for new products including for HYALOFAST, an innovative product for cartilage tissue repair, HYALOBONE, a bone void filler, HYALOSPINE, an innovative adhesion prevention gel for use after spinal surgery, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is currently commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption (“IDE”) to the FDA. Our current plan is to begin a phase III clinical trial for HYALOFAST during the second half of 2015. We completed a HYALOSPINE pilot clinical study in 2012, submitted the CE Mark application in September 2013, and received the CE Mark approval in January 2015.

In February 2014, we received FDA approval for MONOVISC, and Mitek began selling the product in the United States in the second quarter of 2014. MONOVISC is the first FDA-approved, single-injection treatment for osteoarthritis that uses non-animal sourced HA. It is also our first osteoarthritis product based on our proprietary, cross-linked HA technology. We received CE Mark approval for MONOVISC in October 2007, and we began selling in Europe through our distribution network during the second quarter of 2008.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our HA material with an added active therapeutic molecule designed to provide both short- and long-term pain relief to patients. During the second quarter of 2013, we commenced a phase III clinical trial to obtain the needed clinical data for a CE Mark submission and approval and to support other product registrations, including in the United States. We completed the CINGAL clinical trial and associated statistical analysis during the fourth quarter of 2014. In December 2014, we submitted an application for CE Mark approval of the product, and we submitted a Pre-Market Application to the FDA for U.S. marketing approval in February 2015. During the first quarter of 2015, we completed patient enrollment for a retreatment study related to CINGAL with patients who had participated in the initial clinical trial, and we expect to report safety data in the third quarter of this year.

Results of Operations

Three Months Ended March 31, 2015 Compared to the Three Months Ended March 31, 2014

	Three Months Ended March 31,		Inc/(Dec)	
	2015	2014		
Product revenue	\$ 15,514,682	\$ 14,351,405	8	%
Licensing, milestone and contract revenue	5,642	19,658,882	(100	%)
Total revenue	15,520,324	34,010,287	(54	%)
Operating expenses:				
Cost of product revenue	4,313,440	4,361,019	(1	%)
Research & development	2,097,762	2,287,715	(8	%)
Selling, general & administrative	3,604,661	3,490,985	3	%
Total operating expenses	10,015,863	10,139,719	(1	%)
Income from operations	5,504,461	23,870,568	(77	%)
Interest income, net	23,723	467	4980	%
Income before income taxes	5,528,184	23,871,035	(77	%)
Provision for income taxes	2,012,627	8,840,782	(77	%)
Net income	\$ 3,515,557	\$ 15,030,253	(77	%)
Product gross profit	\$ 11,201,242	\$ 9,990,386	12	%
Product gross margin	72	%	70	%

Product Revenue

Product revenue for the quarter ended March 31, 2015 was \$15,514,682, an increase of 8%, as compared to \$14,351,405 for the quarter ended March 31, 2014. Increases in product revenue from our Orthobiologics, Dermal, Veterinary, and Ophthalmic franchises were partially offset by timing related decreases in revenue from our Surgical products.

The following table presents product revenue by group for the three month periods ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Increase (Decrease)	
	2015	2014	\$	%
Orthobiologics	\$ 11,972,500	\$ 11,572,150	\$ 400,350	3 %
Dermal	416,183	188,651	227,532	121 %
Surgical	1,389,595	1,752,020	(362,425)	(21 %)
Ophthalmic	504,472	208,584	295,888	142 %
Veterinary	1,231,932	630,000	601,932	96 %
	\$ 15,514,682	\$ 14,351,405	\$ 1,163,277	8 %

Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 3% for the three months ended March 31, 2015, as compared to the same period in 2014. The growth in the first quarter of 2015 reflected increased revenue from international ORTHOVISC and MONOVISC sales. We expect orthobiologics revenue to grow in 2015, led by increased MONOVISC revenue in the United States, as well as overall revenue growth from our viscosupplementation products both domestically and internationally.

Dermal

Our dermal franchise consists of advanced wound care products, which are based on the HYAFF technology, and aesthetic dermal fillers. Our advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers, with HYALOMATRIX and HYALOFILL as the lead products. For the three month period ended March 31, 2015, dermal product sales increased 121% to \$416,183, as compared to the same period in 2014. The increase primarily reflects revenue from the agreement we entered into in July 2014, with Medline Industries, Inc. to commercialize HYALOMATRIX in the United States on an exclusive basis through 2019. We expect advanced wound care revenue to increase in 2015 compared to 2014 primarily as a result of geographic expansion, particularly in the U.S. market.

Surgical

Our surgical franchise consists of products used to prevent post-surgical adhesions in abdominal-pelvic, spinal, and ear, nose, and throat (“ENT”) disorders. Sales of our surgical products decreased 21% for the three month period ended March 31, 2015 to \$1,389,595, as compared to the same periods in 2014. The decrease of surgical product revenue was primarily due to order timing by our distribution partners. For the full year 2015, we expect revenue from our surgical products to be at a similar level as compared to 2014.

Ophthalmic

Our ophthalmic franchise consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales increased 142% to \$504,472, for the three month period ended March 31, 2015, as compared to the same period in 2014. The increase was primarily attributable to order timing and strong first quarter demand from customers for our ophthalmic products in the United States. For the full year 2015, we expect ophthalmic revenue to decrease due to the termination of the Bausch & Lomb supply agreement for AMVISC, which expired as expected at the end of 2014. Operating margins under this agreement were low, and given that the ophthalmic franchise is not part of our core business, and that it has been steadily diminishing for the past few years, we do not expect this event to have a material impact on our results going forward.

Veterinary

Veterinary revenue from HYVISC increased by 96% to \$1,231,932 for the three month period ended March 31, 2015, as compared to the same period in 2014. The increase was primarily due to order timing and increased demand from our distribution partner, Boehringer Ingelheim Vetmedica Inc. We expect the overall veterinary revenue to be higher in 2015, as compared to 2014, due to increased demand for the product in the United States. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Licensing, milestone, and contract revenue

Licensing, milestone, and contract revenue for the three month period ended March 31, 2015 was \$5,642 as compared to \$19,658,882 for the same period in 2014. The year over year decrease was primarily the result of the recognition of licensing and milestone revenue during the quarter ended March 31, 2014 of \$17,500,000 for milestone payments resulting from the resolution of the patent litigation with Genzyme and the FDA approval of MONOVISC. It also included the recognition of approximately \$2,200,000 unamortized upfront payment previously received in December 2011. These payments were related to development obligations under the Mitek MONOVISC Agreement. The FDA’s approval of our MONOVISC product during the quarter-ended March 31, 2014 completed the delivery of development obligations under the Mitek MONOVISC Agreement, and resulted in the immediate recognition of the \$17,500,000 milestone payment, as well as the full recognition of prior deferred revenue in the first quarter of 2014. We expect that our licensing, milestone, and contract revenue will decrease in 2015 compared to 2014 in large part

due to the multiple significant milestones achieved by us in 2014 in relation to our commercial agreement with Mitek.

Product gross profit and margin

Product gross profit for the three months ended March 31, 2015 increased \$1,210,856 to \$11,201,242 or 72% of product revenue for the period then ended, compared to 70% of product revenue for the period ended March 31, 2014. The increase in product gross margin for the three-month period ended March 31, 2015, as compared to the same period in 2014, is attributable to more favorable revenue mix. This quarter's product gross margin may not be indicative of the rest of the year due to dynamics such as future revenue mix.

Research and development

Research and development expenses for the three month period ended March 31, 2015 were \$2,097,762, or 14% of total revenue, a decrease of \$189,953 compared to the same period in 2014. The decrease in research and development expenses is primarily due to the timing and higher level of clinical activities related to the CINGAL pivotal study in the first quarter of 2014 compared with a smaller scale CINGAL retreatment study in the first quarter of 2015. Research and development spending is expected to increase in future quarters as we further develop new products and initiate new clinical trials based on our existing technology assets.

Selling, general, and administrative

Selling, general, and administrative (“SG&A”) expenses for the three month period ended March 31, 2015 were \$3,604,661, representing 23% of total revenue, an increase of \$113,676. SG&A expenses increased for the three month period ending March 31, 2015, as compared to the same periods in 2014, primarily as a result of increases in personnel related costs, including stock based compensation expenses, as well as external professional fees. We expect SG&A expenses to increase in 2015, as compared to 2014, reflective of the support required to grow our business both domestically and internationally.

Income taxes

Provisions for income taxes were \$2,012,627 and \$8,840,782 for the three month periods ended March 31, 2015 and 2014, respectively, based on effective tax rates of 36.4% and 37.0%. The decrease in income taxes over the three month period ended March 31, 2014 was primarily due to decreased net income as a result of the approximately \$19.7 million in milestone and contract revenue recognized for the three months ended March 31, 2014 associated with the Company’s U.S. license agreement for MONOVISC. The decrease in the effective tax rate over the three month period ended March 31, 2014 was primarily due to an increase in the expected tax benefit of the domestic production deduction.

Liquidity and Capital Resources

We require cash to fund our operating expenses and capital expenditures. We expect that our requirements for cash to fund operations will increase as the scope of our operations expands. Historically, we have generated positive cash flow from operations, which together with our available cash and investments have met our cash requirements. Cash, cash equivalents, and investments totaled approximately \$112.3 million and \$106.9 million at March 31, 2015 and December 31, 2014, respectively. Working capital totaled approximately \$139.8 million at March 31, 2015 and \$133.1 million at December 31, 2014. We believe that we have adequate financial resources to support our business for at least the next twelve months.

Cash provided by operating activities was \$3,983,834 for the three months ended March 31, 2015, as compared to cash provided by operating activities of \$13,596,657 for the same period in the prior year. The decrease in cash provided by operations was due primarily to decreased net income in the first quarter of 2015 compared to the same period last year, which reflected \$19.7 million in milestone and contract revenue associated with our U.S. license agreement for MONOVISC.

Cash used in investing activities was \$6,006,020 for the three months ended March 31, 2015, as compared to cash used in investing activities of \$276,513 for the same period in 2014. The increase in cash used in investing activities is primarily the result of the purchase of investments during the first quarter of 2015.

Cash provided by financing activities was \$1,897,445 for the three months ended March 31, 2015, as compared to cash provided by financing activities of \$5,504,016 for the same period in 2014. The decrease in cash provided by financing activities in the first quarter 2015 is attributable to the fewer tax benefits received in regards to employees’ exercise of stock options compared to the first three months of 2014.

Critical Accounting Estimates

There were no other significant changes in our critical accounting estimates during the three months ended March 31, 2015, as compared to the critical accounting estimates disclosed in Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Recent Accounting Pronouncements

A discussion of Recent Accounting Pronouncements is included in Note 2 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and updated as necessary in Note 2 to the condensed consolidated financial statements included in this quarterly report.

Contractual Obligations and Other Commercial Commitments

Our contractual obligations and other commercial commitments are summarized in the section captioned “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2014. We have had no material changes outside the ordinary course to our contractual obligations during the first three months of 2015.

To the extent that funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

Off-balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing techniques, except for operating leases, that we believe have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

3.

Our market risks, and the ways we manage them, are summarized in the section captioned “Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2014. There have been no material changes in the first three months of 2015 to our market risks or to our management of such risks.

ITEM 4. CONTROLS AND PROCEDURES

4.

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in SEC rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the three-month period ended March 31, 2015 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are involved in various legal proceedings arising in the normal course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to

have a material adverse effect on our financial position, results of operations, or cash flow. During the first three months of 2015, there have been no material changes to the information provided in the section captioned “Part I, Item 3. Legal Proceedings” from our Annual Report on Form 10-K for the year ended December 31, 2014.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors described in the section captioned “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

ITEM 6. EXHIBITS

Exhibit No.	Description
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Sylvia Cheung pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32)	Section 1350 Certifications
**32.1	Certification of Charles H. Sherwood, Ph.D., and Sylvia Cheung, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	XBRL
101*	The following materials from Anika Therapeutics, Inc.’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the SEC on May 4, 2015, formatted in XBRL (eXtensible Business Reporting Language), as follows:
i.	Condensed Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014
ii.	Condensed Consolidated Statements of Operations and Comprehensive Income for the Three Months Ended March 31, 2015 and March 31, 2014 (unaudited)
iii.	Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and March 31, 2014 (unaudited)
iv.	Notes to Condensed Consolidated Financial Statements (unaudited)

* Filed herewith

** Furnished herewith.

SIGNATURES

Pursuant to the requirements 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.

ANIKA THERAPEUTICS, INC.

Date: May 4, 2015

By:

/s/ SYLVIA CHEUNG
Sylvia Cheung
Chief Financial Officer
(Authorized Officer and Principal Financial
Officer)