

Anika Therapeutics, Inc.
Form 10-Q
November 03, 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
X ACT OF 1934**

For the quarterly period ended September 30, 2015

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

For the transition period from to

Commission File Number 000-21326

Anika Therapeutics, Inc.

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

(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 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 No

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

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Non-accelerated filer

Smaller reporting

Large accelerated filer Accelerated filer (Do not check if a smaller

company

reporting company)

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 October 29, 2015 there were 14,637,666 outstanding shares of Common Stock, par value \$.01 per share.

ANIKA THERAPEUTICS, INC.

TABLE OF CONTENTS

	Page
<u>Part I</u>	
<u>Item 1. Financial Statements (unaudited):</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2015 and 2014</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014</u>	<u>5</u>
<u>Notes to condensed consolidated financial statements</u>	<u>6</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>13</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>19</u>
<u>Item 4. Controls and Procedures</u>	<u>19</u>
<u>Part II</u>	
<u>Item 1. Legal Proceedings</u>	<u>19</u>
<u>Item 1A. Risk Factors</u>	<u>19</u>
<u>Item 6. Exhibits</u>	<u>20</u>
<u>Signatures</u>	<u>21</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	September 30, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	\$ 108,469,021	\$ 100,155,864
Investments	22,007,370	6,750,000
Accounts receivable, net of reserves of \$135,618 and \$146,618 at September 30, 2015 and December 31, 2014, respectively	23,375,657	17,152,028
Inventories	12,075,157	12,406,776
Prepaid income taxes	-	412,301
Current portion deferred income taxes	1,409,328	1,188,768
Prepaid expenses and other	947,119	959,305
Total current assets	168,283,652	139,025,042
Property and equipment, at cost	57,667,111	53,619,589
Less: accumulated depreciation	(23,869,798)	(21,950,706)
	33,797,313	31,668,883
Long-term deposits and other	69,020	69,042
Intangible assets, net	12,987,683	14,894,710
Goodwill	7,713,039	8,338,699
Total assets	\$ 222,850,707	\$ 193,996,376
 LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,220,734	\$ 1,201,226
Accrued expenses	6,547,775	4,747,526
Deferred revenue	33,948	24,510
Income taxes payable	4,442,342	-
Total current liabilities	13,244,799	5,973,262
Other long-term liabilities	803,571	893,935
Long-term deferred revenue	73,964	102,192
Deferred tax liability	8,974,122	8,929,890
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
	150,115	148,517

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

Common stock, \$.01 par value; 30,000,000 shares authorized, 15,011,512 and 14,851,703 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively

Additional paid-in-capital	81,052,103	77,539,699
Accumulated other comprehensive loss	(6,066,627)	(4,494,800)
Retained earnings	124,618,660	104,903,681
Total stockholders' equity	199,754,251	178,097,097
Total Liabilities and Stockholders' Equity	\$222,850,707	\$193,996,376

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****(unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Product revenue	\$23,675,696	\$21,975,312	\$62,088,410	\$57,593,873
Licensing, milestone and contract revenue	5,561	80,111	16,732	24,746,497
Total revenue	23,681,257	22,055,423	62,105,142	82,340,370
Operating expenses:				
Cost of product revenue	5,175,723	5,724,800	14,763,222	15,418,732
Research & development	2,061,689	1,999,867	5,971,771	6,160,740
Selling, general & administrative	3,308,731	4,044,538	10,301,886	11,401,399
Total operating expenses	10,546,143	11,769,205	31,036,879	32,980,871
Income from operations	13,135,114	10,286,218	31,068,263	49,359,499
Interest income, net	33,667	9,937	81,297	16,339
Income before income taxes	13,168,781	10,296,155	31,149,560	49,375,838
Provision for income taxes	4,788,916	4,125,355	11,434,581	18,872,435
Net income	\$8,379,865	\$6,170,800	\$19,714,979	\$30,503,403
Basic net income per share:				
Net income	\$0.56	\$0.42	\$1.32	\$2.09
Basic weighted average common shares outstanding	14,967,322	14,758,781	14,944,921	14,626,933
Diluted net income per share:				
Net income	\$0.55	\$0.40	\$1.29	\$1.97
Diluted weighted average common shares outstanding	15,315,808	15,434,875	15,310,758	15,469,237
Net income	\$8,379,865	\$6,170,800	\$19,714,979	\$30,503,403
Other comprehensive income (loss):				
Unrealized gain (loss) on securities, net of tax	2,294	431	(904)	431
Foreign currency translation adjustment	257,521	(1,679,968)	(1,570,923)	(1,896,823)
Total other comprehensive income (loss)	259,815	(1,679,537)	(1,571,827)	(1,896,392)
Comprehensive income	\$8,639,680	\$4,491,263	\$18,143,152	\$28,607,011

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)**

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net income	\$ 19,714,979	\$ 30,503,403
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,800,158	3,576,441
Stock-based compensation expense	1,562,391	1,196,361
Deferred income taxes	(15,873)	-
Provision for inventory	147,560	220,207
Tax benefit from equity awards	(876,797)	(9,236,708)
Changes in operating assets and liabilities:		
Accounts receivable	(6,549,905)	(1,840,407)
Inventories	82,360	(2,923,628)
Prepaid expenses, other current and long-term assets	403,211	183,481
Accounts payable	970,373	(992,822)
Accrued expenses	(120,334)	(989,291)
Deferred revenue	(9,135)	(2,078,543)
Income taxes payable	5,756,972	7,771,001
Other long-term liabilities	(75,777)	(167,123)
Net cash provided by operating activities	23,790,183	25,222,372
Cash flows from investing activities:		
Proceeds from maturity of investments	14,750,000	-
Purchase of investments	(30,008,761)	(19,999,169)
Purchase of property and equipment	(2,028,093)	(920,132)
Net cash used in investing activities	(17,286,854)	(20,919,301)
Cash flows from financing activities:		
Proceeds from exercise of equity awards	1,074,814	1,379,294
Tax benefit from equity awards	876,797	9,236,708
Minimum tax withholdings on share-based awards	-	(6,348,900)
Net cash provided by financing activities	1,951,611	4,267,102
Exchange rate impact on cash	(141,783)	(131,139)
Increase in cash and cash equivalents	8,313,157	8,439,034
Cash and cash equivalents at beginning of period	100,155,864	63,333,160
Cash and cash equivalents at end of period	\$ 108,469,021	\$ 71,772,194
Noncash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 2,197,088	\$ 215,783

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 September 30, 2015, the results of its operations for the three- and nine-month periods ended September 30, 2015 and 2014, and cash flows for the nine-month periods ended September 30, 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- and nine-month periods ended September 30, 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.

A revision was made to the condensed consolidated statement of cash flows for the six months ended June 30, 2014 to correctly reflect the tax benefit from the exercise of certain equity awards. This revision had an impact on the statement of cash flows as a reduction of cash provided by operating activities of approximately \$2.5 million with a corresponding increase to cash provided by financing activities related to the tax benefit from exercise of stock options for the six months ended June 30, 2014 of the same amount. This revision had no impact on the statement of operations or cash position. The revision to the condensed consolidated statement of cash flows noted above represents amounts that are not deemed to be material, individually or in the aggregate, to the prior period condensed consolidated financial statements.

3. Recent Accounting Pronouncements

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 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 is not expected to have a material impact on the Company’s financial position or results of operations.

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's investments at September 30, 2015 and December 31, 2014 are as follows:

	September 30, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	\$3,008,761	\$ -	\$ (1,391)	\$3,007,370
Bank certificates of deposit	19,000,000	-	-	19,000,000
	\$22,008,761	\$ -	\$ (1,391)	\$22,007,370

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

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.

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

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 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	\$57,353,567	\$-	\$57,353,567	\$	-	
Investments:						
Corporate debt securities	\$3,007,370	\$-	\$3,007,370	\$	-	
Bank certificates of deposit	19,000,000	-	19,000,000		-	
Total investments	\$22,007,370	\$-	\$22,007,370	\$	-	
		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 & 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	\$	-	

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 is measured by the grant-date price of the Company’s shares. The fair value of each stock option award during the three- and nine-month periods ended September 30, 2015 and 2014, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,			
	2015		2014	
Risk free interest rate	1.15%	- 1.46%	1.16%	- 1.39%
Expected volatility	53.15%	- 54.65%	53.28%	
Expected life (years)	4.5		4	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$498,442 and \$390,578 of share-based compensation expense for the three-month periods ended September 30, 2015 and 2014, respectively, for equity compensation awards. The Company recorded \$1,562,391 and \$1,196,361 of share-based compensation expense for the nine-month periods ended September 30, 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 no stock options, SARs, Restricted Stock Awards (“RSAs”) or Restricted Stock Units (“RSUs”) granted under the Anika Therapeutics, Inc. Second Amended and Restated 2003 Stock Option and Incentive Plan, as amended (the “Plan”), during the three-month period ended September 30, 2015. During the nine-month period ended September 30, 2015, the Company granted under the Plan a total of 111,625 stock options, 23,375 RSAs, and 9,678 RSUs. All of the RSUs were granted to directors of the Company. 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 nine-month period ended September 30, 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 multiplied by the expected number of shares to be issued, which is adjusted based on the estimated probabilities of achieving the performance goals.

As of September 30, 2015, there was approximately \$4.5 million of total unrecognized compensation cost related to non-vested stock options, SARs, RSAs, and RSUs granted under the Plan. This cost is expected to be recognized over a weighted-average period of 2.73 years.

The total intrinsic value of stock options and SARs exercised during the nine-month periods ended September 30, 2015 and 2014 was \$3,165,838 and \$25,473,089, respectively. Cash received from the exercise of stock options during the three-month periods ended September 30, 2015 and 2014 was \$105,785 and \$17,513, respectively. Cash received from the exercise of options during the nine-month periods ended September 30, 2015 and 2014 was \$1,074,814 and \$1,379,294, respectively. During the second quarter of 2014, the Company acquired and subsequently retired 133,774 common shares related to an employee SARs exercise to meet minimum statutory tax withholding requirements.

There were 812,457 options and SARs outstanding under the Plan as of September 30, 2015 with a weighted-average exercise price of \$17.92 per share, an aggregate intrinsic value of approximately \$12.9 million, and a weighted-average remaining contractual term of 6.7 years. None of the options or SARs outstanding at September 30, 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.

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:

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

	Three Months Ended		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Shares used in the calculation of basic earnings per share	14,967,322	14,758,781	14,944,921	14,626,933
Effect of dilutive securities:				
Stock options, SARs, and RSAs	348,486	676,094	365,837	842,304
Diluted shares used in the calculation of earnings per share	15,315,808	15,434,875	15,310,758	15,469,237

Equity awards of 230,880 and 215,723 shares were outstanding for the three- and nine-month periods ended September 30, 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. Equity awards of 122,967 and 118,725 shares were outstanding for the three- and nine-month periods ended September 30, 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.

8. Inventories

Inventories consist of the following:

	September 30, 2015	December 31, 2014
Raw materials	\$4,861,828	\$6,161,363
Work-in-process	3,924,389	3,041,227
Finished goods	3,288,940	3,204,186
Total	\$12,075,157	\$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.

9. 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.

In January 2015 the Company received CE Mark approval for HYALOSPINE which is an innovative adhesion prevention gel for use after spinal surgery, and was a component of the IPR&D intangible assets initially identified. 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 September 30, 2015 and December 31, 2014 consist of the following:

	Gross Value	September 30, 2015		Accumulated Amortization	Net Book Value	December 31, 2014	
		Current Period Completed Projects	Accumulated Currency Translation Adjustment			Net Book Value	Useful Life
Developed technology	\$ 16,700,000	\$ 400,000	\$ (2,963,427)	\$ (5,706,488)	\$ 8,430,085	\$ 9,409,937	15
In-process research & development	5,502,686	(400,000)	(1,202,735)	-	3,899,951	4,652,874	Indefinite
Distributor relationships	4,700,000	-	(415,344)	(4,284,656)	-	-	5
Patents	1,000,000	-	(178,071)	(320,968)	500,961	581,199	16
Eleves trade name	1,000,000	-	-	(843,314)	156,686	250,700	9
Total	\$ 28,902,686	\$-	\$ (4,759,577)	\$ (11,155,426)	\$ 12,987,683	\$ 14,894,710	

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

The aggregate amortization expense related to intangible assets was \$266,863 and \$518,699 for the three-month periods ended September 30, 2015 and 2014, respectively. The aggregate amortization expense related to intangible assets was \$802,643 and \$1,593,260 for the nine-month periods ended September 30, 2015 and 2014, respectively.

Changes in the carrying value of goodwill for the nine-month periods ended September 30, 2015 and 2014 were as follows:

Goodwill	Nine Months Ended September 30, 2015	Twelve Months Ended December 31, 2014
Balance, beginning	\$8,338,699	\$9,443,894
Effect of foreign currency adjustments	(625,660)	(1,105,195)
Balance, ending	\$7,713,039	\$8,338,699

10. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Compensation and related expenses	\$2,806,699	\$ 2,791,935
Facility construction costs	2,073,561	-
Professional fees	524,938	553,630
Clinical trial costs	240,987	508,042
Research grants	393,085	539,053
Other	508,505	354,866
Total	\$6,547,775	\$ 4,747,526

11. 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 September 30, 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.

12. U.S. Monovisc Commercial Partnership 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 Orthopedic, 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 lawsuit 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 Centers 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.

13. Income Taxes

Provisions for income taxes were \$4,788,916 and \$11,434,581 for the three- and nine-month periods ended September 30, 2015, respectively, based on effective tax rates of 36% and 37%. Provisions for income taxes were \$4,125,355 and \$18,872,435 for the three- and nine-month periods ended September 30, 2014, respectively, based on effective tax rates of 40% and 38%. The increase in income taxes over the three-month period ended September 30, 2015 resulted from higher net income as compared to the same period last year. The decrease in income taxes over the nine-month period ended September 30, 2014 was primarily due to decreased net income as a result of the approximately \$24.7 million in milestone and contract revenue recognized for the nine months ended September 30, 2014 associated with the Company's U.S. license agreement for MONOVISC. See the previous discussion under Note 12. The decrease in the effective tax rate for each of the three- and nine-month periods ended September 30, 2015, as compared to the same periods in 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 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 September 30, 2015 or December 31, 2014.

14. 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		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Orthobiologics	\$20,461,181	\$18,899,873	\$51,716,600	\$48,750,277
Dermal	412,357	401,355	1,131,657	938,966
Surgical	1,413,039	1,452,946	4,449,639	4,581,496
Ophthalmic	344,119	366,138	1,263,582	938,134
Veterinary	1,045,000	855,000	3,526,932	2,385,000
	\$23,675,696	\$21,975,312	\$62,088,410	\$57,593,873

Total revenue by geographic location and as a percentage of overall total revenue for the three- and nine-month periods ended September 30, 2015 and 2014 are as follows:

Three Months Ended September 30,	
2015	2014

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

	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
Geographic Location:				
United States	\$19,239,247	81 %	\$18,455,167	84 %
Europe	1,976,751	8 %	1,784,414	8 %
Other	2,465,259	11 %	1,815,842	8 %
Total	\$23,681,257	100 %	\$22,055,423	100 %

	Nine Months Ended September 30,			
	2015		2014	
Geographic Location:	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
United States	\$51,048,132	82 %	\$72,935,722	89 %
Europe	6,293,965	10 %	5,274,071	6 %
Other	4,763,045	8 %	4,130,577	5 %
Total	\$62,105,142	100 %	\$82,340,370	100 %

15. Subsequent Event

On October 9, 2015, Anika S.r.l. entered into a build-to-suit lease agreement for a new European headquarters facility, consisting of approximately 25,000 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. The Lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The Lease provides for an initial yearly rent of €360,000.

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, 2014, 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 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., commercializes over 20 products, 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		
<i>Advanced wound care</i>		X
Aesthetic dermatology	X	
Surgical		
<i>Anti-adhesion</i>	X	X
Ear, nose and throat care (“ENT”)		X
Ophthalmic	X	
Veterinary	X	

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 HYALOFAST, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, including for CINGAL, 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.

Our wholly owned subsidiary, Anika S.r.l., enhances 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, 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 (“IDE”) to the FDA, which was approved in July 2015. We are preparing for the phase III clinical trial for HYALOFAST, with the expectation that patient enrollment will commence by the end of the year. Another of our products, HYALOSPINE, is an innovative adhesion prevention gel for use after spinal surgery. 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. In June 2015, we submitted an IDE to the FDA to conduct a phase III clinical trial to support the expanded use of MONOVISC for the treatment of pain associated with osteoarthritis of the hip, which was approved by the FDA in July 2015. The associated study will be sponsored by Mitek, and the current plan is for Mitek to begin enrolling patients in U.S. investigational sites in the fourth quarter of 2015.

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 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. In May 2015, we also submitted an application for regulatory approval of CINGAL to Health Canada. We received notification of approval for CINGAL from Health Canada in early November 2015. During the first quarter of 2015, we commenced a retreatment study related to CINGAL with patients who had participated in the initial clinical trial, and we completed the study, as well as the associated statistical analysis, and reported safety data during the second quarter of this year. We conducted a formal meeting with the FDA's Office of Combination Products ("OCP") during September 2015 to present and discuss our data. This meeting resulted in the subsequent submission of a formal request for designation with OCP in October 2015 through which we expect to receive a definitive response related to the regulatory pathway for CINGAL by the end of the year.

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 move towards commercialization as early as 2017.

Results of Operations**Three and Nine Months Ended September 30, 2015 Compared to the Three and Nine Months Ended September 30, 2014**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	% Inc/(Dec)	2015	2014	% Inc/(Dec)
Product revenue	\$23,675,696	\$21,975,312	8 %	\$62,088,410	\$57,593,873	8 %
Licensing, milestone and contract revenue	5,561	80,111	(93 %)	16,732	24,746,497	(100 %)
Total revenue	23,681,257	22,055,423	7 %	62,105,142	82,340,370	(25 %)
Operating expenses:						
Cost of product revenue	5,175,723	5,724,800	(10 %)	14,763,222	15,418,732	(4 %)
Research & development	2,061,689	1,999,867	3 %	5,971,771	6,160,740	(3 %)
Selling, general & administrative	3,308,731	4,044,538	(18 %)	10,301,886	11,401,399	(10 %)
Total operating expenses	10,546,143	11,769,205	(10 %)	31,036,879	32,980,871	(6 %)
Income from operations	13,135,114	10,286,218	28 %	31,068,263	49,359,499	(37 %)
Interest income, net	33,667	9,937	239 %	81,297	16,339	398 %
Income before income taxes	13,168,781	10,296,155	28 %	31,149,560	49,375,838	(37 %)
Provision for income taxes	4,788,916	4,125,355	16 %	11,434,581	18,872,435	(39 %)
Net income	\$8,379,865	\$6,170,800	36 %	\$19,714,979	\$30,503,403	(35 %)
Product gross profit	\$18,499,973	\$16,250,512	14 %	\$47,325,188	\$42,175,141	12 %
Product gross margin	78%	74%		76%	73%	

Product Revenue

Product revenue for the quarter ended September 30, 2015 was \$23,675,696, an increase of 8%, as compared to \$21,975,312 for the quarter ended September 30, 2014. Product revenue for the nine-month period ended September 30, 2015 was \$62,088,410, an increase of 8%, as compared to \$57,593,873 for the nine-month period ended September 30, 2014. For the three months ended September 30, 2015, increases in product revenue from our Orthobiologics, Dermal, and Veterinary franchises were partially offset by moderate decreases in revenue as a result of the timing of orders for our Surgical and Ophthalmic products. Included in product revenue for the three-month periods ended June 30, and September 30, 2015 were approximately \$1.8 million and \$0.5 million, respectively, of non-recurring revenue related to a high end-user average selling price for MONOVISC products sold to our U.S. partner, Mitek, prior to the fourth quarter of 2014. Products sold to Mitek after the third quarter of 2014 are not impacted by this arrangement, which will not result in additional related revenue. For the nine-month period ended September 30, 2015, product revenue grew in all franchises, both domestically and internationally, with the exception

of our Surgical franchise, which decreased slightly year-over-year primarily due to the unfavorable impact from foreign currency exchange rate fluctuations.

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

The following tables present product revenue by group for the three- and nine-month periods ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	
	2015	2014	\$	%
Orthobiologics	\$20,461,181	\$18,899,873	\$1,561,308	8 %
Dermal	412,357	401,355	11,002	3 %
Surgical	1,413,039	1,452,946	(39,907)	(3 %)
Ophthalmic	344,119	366,138	(22,019)	(6 %)
Veterinary	1,045,000	855,000	190,000	22 %
	\$23,675,696	\$21,975,312	\$1,700,384	8 %

	Nine Months Ended September 30,		Increase (Decrease)	
	2015	2014	\$	%
Orthobiologics	\$51,716,600	\$48,750,277	\$2,966,323	6 %
Dermal	1,131,657	938,966	192,691	21 %
Surgical	4,449,639	4,581,496	(131,857)	(3 %)
Ophthalmic	1,263,582	938,134	325,448	35 %
Veterinary	3,526,932	2,385,000	1,141,932	48 %
	\$62,088,410	\$57,593,873	\$4,494,537	8 %

Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 8% and 6% for the three and nine months ended September 30, 2015, respectively, as compared to the same periods in 2014. The growth in the third quarter of 2015 reflected a growing end-user demand, increased revenue from international ORTHOVISC and worldwide MONOVISC sales, as well as the non-recurring product revenue discussed in the prior section. These increases were partially offset by decreases in product sales to Mitek as a result of its planned reduction in inventory, which was completed during the third quarter of 2015. We expect orthobiologics revenue to continue 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- and nine-month periods ended September 30, 2015, dermal product sales increased 3% and 21%, respectively, as compared to the same periods in 2014. The increase for the nine-month period 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 due to geographic expansion, and particularly in the U.S. market as a result of the grant of reimbursement eligibility by the Centers for Medicare & Medicaid Services for HYALOMATRIX in 11 states and Washington D.C.

Surgical

Our surgical franchise consists of products used to prevent post-surgical adhesions after abdominal-pelvic, spinal, and ear, nose, and throat (“ENT”) surgeries. Sales of our surgical products decreased 3% for the three- and nine-month periods ended September 30, 2015 to \$1,413,039 and \$4,449,639, respectively, as compared to the same periods in 2014. The decreases of surgical product revenue for both the three- and nine-month periods was primarily due to the unfavorable impact from foreign currency exchange rate fluctuations compared with the same periods in the prior year. We expect the unfavorable foreign currency impact will contribute to a slightly lower full year surgical product revenue in 2015, as compared to 2014.

Ophthalmic

Our ophthalmic franchise consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales decreased 6% and increased 35%, respectively, for the three- and nine-month periods ended September 30, 2015, to \$344,119 and \$1,263,582 as compared to the same periods in 2014. The increase for the nine-month period 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 22% and 48% to \$1,045,000 and \$3,526,932 for the three- and nine-month periods ended September 30, 2015, as compared to the same periods in 2014. The growth in HYVISC demand was a result of increased sales and marketing efforts by our distribution partner, Boehringer Ingelheim. 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- and nine-month periods ended September 30, 2015 was \$5,561 and \$16,732 respectively as compared to \$80,111 and \$24,746,497 for the same periods in 2014. The year over year decrease was primarily the result of the recognition of licensing and milestone revenue through the nine months ended September 30, 2014 of \$22,500,000 for milestone payments related to development obligations under the Mitek MONOVISC Agreement. It also included the recognition of approximately \$2,200,000 unamortized upfront payments previously received in December 2011. The FDA's approval of our MONOVISC product during the first quarter in 2014 completed the delivery of development obligations under the Mitek MONOVISC Agreement, and it resulted in the immediate recognition of a \$17,500,000 milestone payment, as well as the full recognition of prior deferred revenue in that quarter. During the second quarter of 2014, a \$5,000,000 milestone payment associated with the first commercial sale of MONOVISC in the United States was also earned, received, and recognized as revenue. 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 for MONOVISC in the U.S.

Product gross profit and margin

Product gross profit for the three and nine months ended September 30, 2015 was \$18,499,973 and \$47,325,188, or 78% and 76% of product revenue for each period, respectively. Product gross margin for the three- and nine-month periods ended September 30, 2014 was \$16,250,512 and \$42,175,141, or 74% and 73% of the product revenue for each period, respectively. The increase in product gross margin for the three- and nine-month periods ended September 30, 2015, as compared to the same periods in 2014, was attributable to a more favorable revenue mix and continued efficiency gains at our Bedford, Massachusetts facility. 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- and nine-month periods ended September 30, 2015 were \$2,061,689 and \$5,971,711, or 9% and 10% of total revenue for each period, respectively. Research and development expenses increased \$61,822 and decreased \$188,969 for the three- and nine-month periods ended September 30, 2015, respectively, as compared to the same periods in 2014. The decrease in research and development expenses for the nine-months was primarily due to the timing of and higher level of clinical activities related to the CINGAL pivotal study in 2014 compared with the smaller scale CINGAL retreatment study in 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, including HYALOFAST.

Selling, general, and administrative

Selling, general, and administrative (“SG&A”) expenses for the three- and nine-month periods ended September 30, 2015 were \$3,308,731 and \$10,301,886, representing 14% and 17% of total revenue, a decrease of \$735,807 and \$1,099,513 compared to the same periods last year, respectively. SG&A expenses decreased for the three- and nine-month periods ending September 30, 2015 primarily as a result of the full amortization of certain intangible assets on December 31, 2014, certain former employee termination and related expenses in 2014, as well as beneficial impact from foreign currency exchange rate fluctuations. We expect SG&A expenses to increase for the full year 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 \$4,788,916 and \$11,434,581 for the three- and nine-month periods ended September 30, 2015, respectively, based on effective tax rates of 36% and 37%. Provisions for income taxes were \$4,125,355 and \$18,872,435 for the three- and nine-month periods ended September 30, 2014, respectively, based on effective tax rates of 40% and 38%. The decrease in the effective tax rate for each of the three- and nine-month periods ended September 30, 2015, as compared to the same periods in 2014, was primarily due to an increase in the expected tax benefit of the domestic production deduction and an increase in state research and development credit.

Liquidity and Capital Resources

We expect that our requirements for cash to fund operations and capital expenditures 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 \$130.5 million and \$106.9 million at September 30, 2015 and December 31, 2014, respectively. Working capital totaled approximately \$155.0 million at September 30, 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 \$23,790,183 for the nine months ended September 30, 2015, as compared to cash provided by operating activities of \$25,222,372 for the same period in the prior year. The decrease in cash provided by operations was due primarily to decreased net income for the nine months ended September 30, 2015 compared to the same period last year, which reflected \$24.7 million in milestone and contract revenue associated with our U.S. license agreement for MONOVISC. Cash provided by operations was also impacted by an increase in net working capital requirements as compared to the same period in 2014 related to higher accounts receivable and the timing of sales during the year, which was partially offset by lower inventory levels.

Cash used in investing activities was \$17,286,854 for the nine months ended September 30, 2015, as compared to cash used in investing activities of \$20,919,301 for the same period in 2014. The decrease in cash used in investing activities was primarily the result of the purchase of investments offset by maturities of investments during the first half of 2015. We expect an increase in investing activities in 2015 as a result of our on-going project to establish additional manufacturing capabilities at the Bedford, Massachusetts facility to manufacture our HYAFF-based products, which currently are manufactured by a third party. We expect to expend approximately \$25 million on this project over the course of the next 18 to 24 months.

Cash provided by financing activities was \$1,951,611 for the nine months ended September 30, 2015, as compared to cash provided by financing activities of \$4,267,102 for the same period in 2014. The decrease in cash provided by financing activities through the nine months ended September 30, 2015 was attributable to the lower tax benefits received in regards to employees' exercise of stock options compared to the first nine months of 2014.

Critical Accounting Estimates

There were no other significant changes in our critical accounting estimates during the three months ended September 30, 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and updated in Note 3 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 as reported in our 2014 Annual Report on Form 10-K during the first nine 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

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 nine months of 2015 to our market risks or to our management of such risks.

ITEM 4. CONTROLS AND PROCEDURES

(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 chief 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 our company in the reports it files or submits under the Exchange Act is accumulated and communicated to our 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 September 30, 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. There have been no material changes to the information provided in the section captioned “Part I, Item 3, Legal Proceedings” in 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

- 10.1 Translation of Lease Agreement entered into as of October 9, 2015 by and between Consorzio Zona Industriale E Porto Fluviale di Padova and Anika Therapeutics S.r.l. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed by Anika Therapeutics, Inc. on October 14, 2015)
- (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 September 30, 2015, as filed with the SEC on November 3, 2015, formatted in XBRL (eXtensible Business Reporting Language), as follows:
- i. Condensed Consolidated Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014
 - ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2015 and September 30, 2014 (unaudited)
 - iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and September 30, 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: November 3, 2015 By: /s/ SYLVIA CHEUNG
Sylvia Cheung
Chief Financial Officer
(Authorized Officer and Principal
Financial Officer)

