

Anika Therapeutics, Inc.  
Form 10-Q  
November 06, 2014

**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, 2014**

**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.**

(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.

Large accelerated filer  Accelerated filer  (Do not check if a smaller reporting company)  
Non-accelerated filer  Smaller 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 31, 2014 there were 14,504,014 outstanding shares of Common Stock, par value \$.01 per share.

**PART I: FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**

**Anika Therapeutics, Inc. and Subsidiaries**

**Condensed Consolidated Balance Sheets**

**(unaudited)**

	September 30,	December 31,
ASSETS	2014	2013
Current assets:		
Cash and cash equivalents	\$71,772,194	\$63,333,160
Marketable securities	19,999,600	-
Accounts receivable, net of reserves of \$546,455 and \$593,023 at September 30, 2014 and December 31, 2013, respectively	20,170,095	18,736,845
Inventories	13,582,456	10,996,785
Prepaid income taxes	1,343,576	-
Current portion deferred income taxes	659,040	659,040
Prepaid expenses and other	1,128,693	865,957
Total current assets	128,655,654	94,591,787
Property and equipment, at cost	53,379,965	52,413,423
Less: accumulated depreciation	(21,343,322 )	(19,474,712 )
	32,036,643	32,938,711
Long-term deposits and other	69,054	69,080
Intangible assets, net	16,033,944	18,998,409
Goodwill	8,702,295	9,443,894
Total assets	\$185,497,590	\$156,041,881
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,167,545	\$2,793,911
Accrued expenses	5,253,693	5,537,881
Deferred revenue	12,885	180,433
Income taxes payable	-	770,276
Total current liabilities	6,434,123	9,282,501
Other long-term liabilities	948,858	1,133,544
Long-term deferred revenue	56,573	2,054,941
Deferred tax liability	8,353,531	7,936,864
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
	148,004	142,893

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

Common stock, \$.01 par value; 30,000,000 shares authorized, 14,800,453 and 14,289,308 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively

Additional paid-in-capital	76,064,383	70,606,031
Accumulated other comprehensive loss	(3,595,487 )	(1,699,095 )
Retained earnings	97,087,605	66,584,202
Total stockholders' equity	169,704,505	135,634,031
Total Liabilities and Stockholders' Equity	\$ 185,497,590	\$ 156,041,881

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 September 30,		Nine Months Ended September 30,	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Product revenue	\$21,975,312	\$17,023,346	\$57,593,873	\$51,585,242
Licensing, milestone and contract revenue	80,111	731,092	24,746,497	2,244,584
Total revenue	22,055,423	17,754,438	82,340,370	53,829,826
Operating expenses:				
Cost of product revenue	5,724,800	5,377,568	15,418,732	16,530,070
Research & development	1,999,867	1,618,012	6,160,740	5,029,974
Selling, general & administrative	4,044,538	3,188,669	11,401,399	10,536,462
Restructuring credits	-	(196,084 )	-	(442,869 )
Total operating expenses	11,769,205	9,988,165	32,980,871	31,653,637
Income from operations	10,286,218	7,766,273	49,359,499	22,176,189
Interest income (expense), net	9,937	(32,816 )	16,339	(108,755 )
Income before income taxes	10,296,155	7,733,457	49,375,838	22,067,434
Provision for income taxes	4,125,355	2,776,199	18,872,435	8,147,282
Net income	\$6,170,800	\$4,957,258	\$30,503,403	\$13,920,152
Basic net income per share:				
Net income	\$0.42	\$0.36	\$2.09	\$1.03
Basic weighted average common shares outstanding	14,758,781	13,682,449	14,626,933	13,534,334
Diluted net income per share:				
Net income	\$0.40	\$0.33	\$1.97	\$0.95
Diluted weighted average common shares outstanding	15,434,875	14,958,965	15,469,237	14,673,879
Net income	\$6,170,800	\$4,957,258	\$30,503,403	\$13,920,152
Other comprehensive income (loss):				
Unrealized gain on securities, net of tax	431	-	431	-
Foreign currency translation adjustment	(1,679,968 )	916,474	(1,896,823 )	507,119
Total other comprehensive income (loss)	(1,679,537 )	916,474	(1,896,392 )	507,119
Comprehensive income	\$4,491,263	\$5,873,732	\$28,607,011	\$14,427,271

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,	
	2014	2013
Cash flows from operating activities:		
Net income	\$30,503,403	\$13,920,152
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,576,441	3,579,474
Stock-based compensation expense	1,196,361	1,156,929
Provision for doubtful accounts	-	24,098
Provision for inventory	220,207	165,803
Gain on sale of assets	-	(442,341 )
Tax benefit from exercise of stock options	(9,236,708 )	(764,181 )
Changes in operating assets and liabilities:		
Accounts receivable	(1,840,407 )	4,667,839
Inventories	(2,923,628 )	(3,430,655 )
Prepaid expenses, other current and long-term assets	183,481	531,449
Long-term deposits and other	-	25,497
Accounts payable	(992,822 )	124,679
Accrued expenses	(989,291 )	(642,430 )
Deferred revenue	(2,078,543 )	(2,150,000 )
Income taxes	7,771,001	766,598
Other long-term liabilities	(167,123 )	(373,712 )
Net cash provided by operating activities	25,222,372	17,159,199
Cash flows from investing activities:		
Purchase of marketable securities	(19,999,169 )	-
Proceeds from sale of assets	-	530,865
Purchase of property and equipment	(920,132 )	(235,803 )
Net cash provided by (used in) investing activities	(20,919,301 )	295,062
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,379,294	2,932,649
Tax benefit from exercise of stock options	9,236,708	764,181
Minimum tax withholding on share based awards	(6,348,900 )	-
Principal payments on debt	-	(1,200,000 )
Net cash provided by financing activities	4,267,102	2,496,830
Exchange rate impact on cash	(131,139 )	36,870
Increase in cash and cash equivalents	8,439,034	19,987,961
Cash and cash equivalents at beginning of period	63,333,160	44,067,477
Cash and cash equivalents at end of period	\$71,772,194	\$64,055,438

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

4

**ANIKA THERAPEUTICS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**1. Nature of Business**

Anika Therapeutics, Inc. (together with its subsidiaries, “Anika,” the “Company,” “we,” “us,” or “our”) 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 information and technology, commercialization of existing and new products, and compliance with the 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 (“U.S.”). 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 our audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. 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, 2014, the results of its operations for the three and nine-month periods ended September 30, 2014 and 2013, and cash flows for the nine-month periods ended September 30, 2014 and 2013.

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, 2013. The results of operations for the three and nine-month periods ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014. 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 on the condensed consolidated statement of cash flows for the six months ended June 30, 2014 to correctly reflect the tax benefit from exercise of certain equity awards. This revision has an impact on the statement of cash flows as a reduction of cash provided by operating activities of \$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 has no impact on the statement of operations or cash position. The revision to the condensed consolidated statement of cash flows represents amounts that are not deemed to be material, individually or in the aggregate, to the prior period condensed consolidated financial statements.

### 3. Marketable Securities

	September 30, 2014			
	Amortized	Unrealized	Unrealized	Fair
	Cost	Gains, Net of Tax	Losses, Net of Tax	Value
United States Treasury securities	\$ 14,999,169	\$ 699	\$ (268 )	\$ 14,999,600
Bank certificates of deposit	5,000,000	-	-	5,000,000
	\$ 19,999,169	\$ 699	\$ (268 )	\$ 19,999,600

The Company considers securities with maturities of three months or less from the purchase date to be cash equivalents. Interest is recorded when earned. 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.

### 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 in 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 marketable securities at fair value.

The Company's investments are all classified within Level 1 and Level 2 of the fair value hierarchy. The Company's investments classified within Level 1 of the fair value hierarchy are valued using quoted market prices. The Company's 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 marketable securities at fair value is as follows:

		Fair Value Measurements at Reporting		
		Date Using Quoted Prices in	Significant Other	Significant
		Active Markets	Observable Inputs	Unobservable
		for Identical Assets	(Level 2)	Inputs
		(Level 1)		(Level 3)
September 30, 2014				
Money market funds	\$ 49,285,168	\$-	\$ 49,285,168	\$ -
Marketable securities:				
United States Treasury securities	14,999,600	14,999,600	-	-
Bank certificates of deposit	5,000,000	-	5,000,000	-
Total marketable securities	\$ 19,999,600	\$ 14,999,600	\$ 5,000,000	\$ -

		Fair Value Measurements at Reporting		
		Date Using Quoted Prices in	Significant	Unobservable
		Active Markets	Observable Inputs	Inputs
		for Identical Assets	(Level 2)	(Level 3)
		(Level 1)		
December 31, 2013				
Money market funds	\$ 34,266,501	\$-	\$ 34,266,501	\$ -

## **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 and nine-month periods ended September 30, 2014 and 2013, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

**Three Months Ended**

	<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>
Risk free interest rate	1.30%-	1.39% -
Expected volatility	53.28%	-
Expected lives (years)	4	-
Expected dividend yield	0.00%	-

**Nine Months Ended**

	<b>September 30,</b>			
	<b>2014</b>		<b>2013</b>	
Risk free interest rate	1.16%-	1.39%	0.61%-	0.70%
Expected volatility	53.28%		57.60%	
Expected lives (years)	4		4	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$390,578 and \$368,603 of share-based compensation expense for the three-month periods ended September 30, 2014 and 2013, respectively, for equity compensation awards. The Company recorded \$1,196,361 and \$1,156,929 of share-based compensation expense for the nine-month periods ended September 30, 2014 and 2013, 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 7,000 and 139,240 stock options granted under the Plan during the three and nine-month periods ended September 30, 2014, respectively. There were no Restricted Stock Awards (“RSAs”) or Restricted Stock Units (“RSUs”) granted under the Plan during the three-month period ended September 30, 2014. There were 9,365 RSUs granted to members of the Company’s Board of Directors under the Plan during the nine-month period ended September 30, 2014. There were 30,700 RSAs granted to Company employees under the Plan during the nine-month period ended September 30, 2014. The stock options, RSAs and RSUs granted to employees and directors 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, 2014 contained certain performance features, as compared to established targets, in addition to time-based vesting conditions. The compensation costs associated with these grants was estimated using the Black-Scholes valuation method factored for the estimated probability of achieving the performance goals.

As of September 30, 2014, there was approximately \$4.2 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 3.0 years.

The total intrinsic value of stock options and SARs exercised during the nine-month periods ended September 30, 2014 and 2013 was \$25,473,089 and \$4,095,833, respectively. Cash received from the exercise of stock options during the three and nine-month periods ended September 30, 2014 and 2013 were \$17,513 and \$1,379,294, and \$1,804,773 and \$2,932,649, 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 936,097 options and SARs outstanding under the Company's incentive Plans as of September 30, 2014 with a weighted-average exercise price of \$13.54 per share, an aggregate intrinsic value of approximately \$21.8 million, and a weighted-average remaining contractual term of 6.8 years. None of the options or SARs outstanding at September 30, 2014 or 2013, 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

The Company reports earnings per share in accordance with ASC 260, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding and the number of dilutive potential common share equivalents during the period. Under the treasury stock method, unexercised “in-the-money” stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period.

Basic and diluted earnings per share for the three and nine-month periods ended September 30, 2014 and 2013 are as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Shares used in the calculation of basic earnings per share	14,758,781	13,682,449	14,626,933	13,534,334
Effect of dilutive securities:				
Stock options, SARs, and RSAs	676,094	1,276,516	842,304	1,139,545
Diluted shares used in the calculation of earnings per share	15,434,875	14,958,965	15,469,237	14,673,879

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. There were no anti-dilutive equity awards for the three month period ended September 30, 2013. Equity awards of 88,278 shares were outstanding for the nine-month period ended September 30, 2013, 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:

	September 30, December 31,	
	2014	2013
Raw materials	\$6,843,441	\$5,926,030
Work-in-process	2,325,667	2,308,233
Finished goods	4,413,348	2,762,522

Total                   \$ 13,582,456   \$ 10,996,785

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.

## **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. 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.

Intangible assets as of September 30, 2014 and December 31, 2013 consist of the following:

	September 30, 2014			December 31, 2013		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$ 16,700,000	\$(1,828,214)	\$(4,779,123)	\$ 10,092,663	\$ 11,753,003	15
In-process research & development	5,502,686	(638,426 )	-	4,864,260	5,286,127	Indefinite
Distributor relationships	4,700,000	(440,953 )	(4,084,944)	174,103	863,655	5
Patents	1,000,000	(107,910 )	(271,208 )	620,882	719,574	16
Eleves trade name	1,000,000	-	(717,964 )	282,036	376,050	9
Total	\$28,902,686	\$(3,015,503)	\$(9,853,239)	\$ 16,033,944	\$ 18,998,409	

The aggregate amortization expense related to intangible assets was \$518,699 and \$521,387 for the three-month periods ended September 30, 2014 and 2013, respectively. The aggregate amortization expense related to intangible assets was \$1,593,260 and \$1,555,796 for the nine-month periods ended September 30, 2014 and 2013, respectively.

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

Goodwill	Three	Nine
	Months Ended	Months Ended
	September 30,	September 30,
	2014	2014
Balance, beginning	\$ 9,360,884	\$ 9,443,894
Effect of foreign currency adjustments	(658,589 )	(741,599 )
Balance, ending	\$ 8,702,295	\$ 8,702,295

## 9. Accrued Expenses

Accrued expenses consist of the following:



**September 30, December 31,**

	<b>2014</b>	<b>2013</b>
Labor and related expenses	\$ 2,842,234	\$ 2,870,147
Clinical trial costs	962,031	882,651
Professional fees	382,423	383,231
Research grants	562,558	610,498
Restructuring costs	11,909	24,638
Other	492,538	766,716
Total	\$ 5,253,693	\$ 5,537,881

**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 product. The Company may also warrant that the products it manufactures do not infringe, violate or breach any patent or intellectual property rights, 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 negligence or acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure. Based on the Company's historical activity in combination with its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. The Company has no accrued warranties and has no history of claims paid.

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The complaint alleged that the Company infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC® in the United States for sale outside the United States and would infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company manufactured and sold MONOVISC in the United States. On March 7, 2014, Genzyme and the Company filed a joint motion to lift the stay in Genzyme's lawsuit against the Company and to dismiss with prejudice all of Genzyme's claims. On March 10, 2014, the District Court granted the motion to dismiss with prejudice all of Genzyme's claims against the Company and the case was terminated.

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 U.S. The Company received an upfront payment of \$2,500,000 in December 2011. This non-refundable upfront payment did not have standalone value without Anika’s completion of development obligations which included obtaining regulatory approval of the product and resolving the patent litigation. As a result, we 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 represents 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 our commercial partner, DePuy Synthes Mitek Sports Medicine. Under the terms of the Mitek MONOVISC Agreement, the Company earned and collected a milestone payment of \$5 million, which was fully recognized as revenue in the second quarter of 2014.

## **12. Income Taxes**

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%. Provisions for income taxes were \$2,776,199 and \$8,147,282 for the three and nine-month periods ended September 30, 2013, respectively, based on effective tax rates of 36% and 37%, respectively. The increase in income taxes over the three-month period ended September 30, 2014 was primarily due to increased net income. The increase in income taxes over the nine-month period ended September 30, 2014 was primarily due to increased net income, which reflected \$24,652,778 in milestone and contract revenue associated with our U.S. license agreement for MONOVISC. See the previous discussion under Note 11. The increase in the effective tax rate for each of the periods ended 2014, as compared to the same periods ended in 2013, was driven primarily by the unavailability of the federal R&D tax credit in 2014, due to its expiration on December 31, 2013, and a relative decrease to our estimated production activities deduction.

The Company files income tax returns in the U.S. 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. Our 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. Our filings from 2009 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. We have 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, we have not recorded a valuation allowance at September 30, 2014 or December 31, 2013.

### **13. Segment and Geographic Information**

The Company has one reportable operating segment, the results of which are disclosed in the accompanying unaudited condensed consolidated financial statements.

Product revenue by product group is as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Orthobiologics	\$18,899,873	\$12,830,566	\$48,750,277	\$40,620,339
Dermal	401,355	267,766	938,966	1,066,409
Surgical	1,452,946	1,136,248	4,581,496	3,955,134
Ophthalmic	366,138	1,425,609	938,134	2,818,407
Veterinary	855,000	1,363,157	2,385,000	3,124,953
	\$21,975,312	\$17,023,346	\$57,593,873	\$51,585,242

Total revenue by geographic location and as a percentage of overall total revenue, for the three and nine-month periods ended September 30, 2014 and 2013 are as follows;

Geographic Location:	Three Months Ended September 30,		September 30,	
	2014		2013	
	Total	Percentage of	Total	Percentage of
	Revenue	Revenue	Revenue	Revenue
United States	\$18,455,167	84 %	\$14,485,821	82 %
Europe	1,784,414	8 %	1,656,656	9 %
Other	1,815,842	8 %	1,611,961	9 %
Total	\$22,055,423	100 %	\$17,754,438	100 %

Geographic Location:	Nine Months Ended September 30,		September 30,	
	2014		2013	
	Total	Percentage of	Total	Percentage of
	Revenue	Revenue	Revenue	Revenue
United States	\$72,935,722	89 %	\$42,251,336	78 %
Europe	5,274,071	6 %	5,226,619	10 %
Other	4,130,577	5 %	6,351,871	12 %
Total	\$82,340,370	100 %	\$53,829,826	100 %

#### 14. Restructuring Credits

In December 2012, the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the Company's inability to meet strict regulatory standards established by the European Medicines Agency ("EMA") for Advanced Therapy Medicinal Products, which became effective on January 1, 2013. The restructuring plan involved a workforce reduction as well as associated asset abandonments. The Company recorded restructuring and impairment charges in the fourth quarter of 2012 of approximately \$2.5 million. Of the total restructuring and impairment charges related to the tissue engineering operation, approximately \$1.2 million was related to the non-cash termination and related impairment of an IPR&D project, \$0.3 million was related to the disposal of property and equipment, and \$0.1 million was related to the disposal of inventory. We completed the restructuring plan and related activities in 2013. Certain previously impaired and written-off equipment was sold, resulting in restructuring credits of \$196,084 and \$442,869 in the three and nine months ended September 30, 2013, respectively.

The following table summarizes restructuring accrual activity for the nine-period ended September 30, 2014:

	Restructuring Accrual Employee Activity		
	Severance and Related Benefits	Termination and Facility Closure Costs	Total
December 31, 2013	\$21,709	\$ 2,929	\$24,638
Cash Proceeds (Disbursements)	(10,130)	(1,425 )	(11,555)
Foreign Exchange Impact	(1,050 )	(124 )	(1,174 )
September 30, 2014	\$10,529	\$ 1,380	\$11,909

### 15. New Accounting Standards

In June 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," which requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. Thus, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The new guidance is effective for the Company beginning January 1, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In May 2014, the FASB issued 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. ASU 2014-09 is effective retrospectively for annual or interim reporting periods beginning after December 15, 2016, with early application not permitted. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In April 2014, the FASB issued ASU No. 2014-08, "Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity." ASU 2014-08 provides a narrower definition of discontinued operations than that provided under existing U.S. GAAP. ASU 2014-08 requires that only a disposal of a component of an entity, or a group of components of an entity, which disposal represents a strategic shift that has, or will have, a major effect on the reporting entity's operations and financial results, should be reported in the financial statements as a discontinued operation. ASU 2014-08 also provides guidance on the financial statement presentations and disclosures of

discontinued operations. ASU 2014-08 is effective prospectively for disposals (or classifications as held for disposal) of components of an entity that occur in annual or interim periods beginning after December 15, 2014. The Company does not expect the adoption of ASU 2014-08 to have a material impact on its consolidated financial statements.

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

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements regarding:*

Our future sales and product revenue, including geographic expansions, possible retroactive price adjustments, and expectations of unit volumes or other offsets to price reductions;

- Our manufacturing capacity, efficiency gains and work-in-process manufacturing operations;

- The timing, scope and rate of patient enrollment for clinical trials;

- The development of possible line extensions and new products;

- Our ability to achieve and/or maintain compliance with laws and regulations;

The timing of and/or receipt of Food and Drug Administration ("FDA"), foreign or other regulatory approvals, clearances, and/or reimbursement approvals of current, new or potential products, and any limitations on such approvals;

- Our intention to seek patent protection for our products and processes, and to protect our intellectual property;

- Our ability to effectively compete against current and future competitors;

Negotiations with potential and existing partners, including our performance under any of our existing and future distribution, license or supply agreements, and our expectations with respect to sales and sales threshold milestones pursuant to such agreements;

The level of our revenue or sales in particular geographic areas and/or for particular products, and the market share for any of our products;

- Our expectations of product revenue results in future quarters and for the full year 2014;

Our current strategy, including our corporate objectives, research and development activities and collaboration activities;



Our expectations regarding our orthobiologics products, including existing products and expectations regarding new products, expanded uses of existing products, new distribution partnerships and revenue growth;

Our intention to increase our market share for orthobiologics products in domestic and international markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;

Our expectations regarding next generation orthobiologics product development, clinical trials, regulatory approvals and commercial launches;

Our and Bausch & Lomb's performance under the non-exclusive, three-year contract for the supply of AMVISC® and AMVISC® Plus ophthalmic viscoelastic products, our expectations regarding revenue from ophthalmic products, and the impact that such agreement's expiration will have on our results of operations going forward;

Our ability to commercialize ANIKAVISC® and ANIKAVISC® Plus and our expectations regarding such commercialization and the potential profits generated thereby;

Our ability to license our aesthetics product to new distribution partners domestically and outside the U.S., and our expectations regarding development of aesthetics product line extensions;

Our ability and the ability of our distribution partners, to market our aesthetics dermatology product; and our expectations regarding the distribution and sales of our ELEVESS® product and the timing thereof;

Our expectations regarding HYVISC® sales;

· Our expectations regarding product gross margin;

· Our expectations regarding CINGAL<sup>®</sup>, including the expense associated therewith, the timing of submission of our CE Mark application, and our ability to obtain regulatory approvals for this product;

· Possible negotiations or re-negotiations with existing or new distribution or collaboration partners;

· Our ability to continue streamlining operations and improving our manufacturing capabilities;

· Our expectation for changes in operating expenses, including research and development, and selling, general and administrative expenses;

· The rate at which we use cash, the amounts used and generated by operations, and our expectations regarding the adequacy and usage of such cash;

· Our expectation for capital expenditures and future amounts of interest income and expense;

· Our ability to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and other sources, to the extent our current sources of funds are insufficient;

· Our ability to manage the operations of Anika S.r.l. as a company generating continued profits;

· The strength of the economies in which the Company operates or will operate, as well as the political stability of any of those geographic areas;

· Our ability to effectively prioritize the many research and development projects underway;

· Our ability to expand the therapeutic applications of our existing products and create new applications for our HA technology;

· Our ability to obtain U.S. approval for orthopedic and other product franchises of Anika S.r.l., including the timing and potential success of such efforts, and to expand sales of these products in the U.S., including the impact such efforts may have on our revenue; and

· Our ability to successfully defend the Company against lawsuits and claims, and the uncertain financial impact such lawsuits and claims and related defense costs may have on the Company.

*Furthermore, additional statements identified by words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “intend,” “seek,” “designed,” “develop,” “would,” “future,” “can,” “could,” and other expressions that are predictions of or indicate future events and trends and which do not relate to historical matters, also identify forward-looking statements.*

*You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2013. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed herein and in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this Quarterly Report on Form 10-Q, as well as the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2013 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors of new information, future events or other changes.*

**Management Overview**

Anika Therapeutics, Inc. (together with its subsidiaries, “Anika,” the “Company,” “we,” “us,” or “our”) 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.

Anika’s proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to intended therapeutic uses. Our patented technologies chemically modify the HA molecule to allow for longer residence time in the body. Anika Therapeutics, Inc.’s wholly-owned subsidiary, Anika Therapeutics S.r.l., has over 20 products currently commercialized. 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. 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
<i>Aesthetic dermatology</i>	X	
Surgical		
<i>Anti-adhesion</i>		X
<i>Ear, nose and throat care (“ENT”)</i>	X	X
Ophthalmic	X	
Veterinary	X	

Please see Management’s Discussion and Analysis of Financial Condition and Results of Operations-Management Overview (Item 7) to the Company’s Annual Report on Form 10-K for the year ended December 31, 2013, for a description of each of the above therapeutic areas, including the individual products.

**Research and Development**

Anika's research and development efforts primarily consist of the development of new medical applications for our HA-based technologies, the management of clinical trials and studies for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities related to our existing and new products. Our development focus includes products for tissue protection, healing and repair. Our investment in R&D varies considerably depending on the timing, number and size of clinical trials and studies underway. We anticipate that we will commit significant resources to research and development, including clinical trials, in the future.

During the first quarter of 2014, the Company received FDA approval of MONOVISC and resolved the patent lawsuit with Genzyme Corporation. The Company received a milestone payment of \$17,500,000 under the Mitek MONOVISC Agreement related to FDA approval of MONOVISC and the successful resolution of the Genzyme patent litigation. As a result of the full delivery of our development obligations under this agreement, the Company also recognized the remaining balance of deferred revenue relating to the initial \$2,500,000 non-refundable up-front payment. Both amounts were fully recognized as revenue during the three months ended March 31, 2014.

A key product currently under development is CINGAL, which is based on our HA material with an added active therapeutic molecule designed to provide broad pain relief for a longer period of time. We completed the formulation and biocompatibility studies of the product. During the second quarter of 2013, we commenced a multinational phase III clinical trial to obtain the clinical data necessary for a CE Mark submission and approval, and to support other product registrations including in the United States. Enrollment in the clinical trial was completed in February 2014, and the last patient follow-up was completed in September 2014. We expect to submit our CE Mark application by December 31, 2014, or shortly thereafter.

HYALOFAST™ is an innovative biodegradable matrix for human bone marrow mesenchymal stem cells used in connection with soft tissue regeneration. HYALOFAST received CE Mark approval in September 2009, and it is currently commercially available in Europe and certain international countries. During the second quarter of 2014, we submitted a proposed investigational device protocol to the FDA. Our current plan is to begin a phase III clinical trial in 2015.

The technologies obtained through our acquisition of Anika S.r.l. have enhanced our research and development capabilities, and our pipeline of product candidates. Anika S.r.l. has research and development programs for new products including HYALOFAST and HYALOSPINE™, an adhesion prevention gel for use after spinal surgery. Our research and development efforts may not be successful in (1) developing our existing product candidates, (2) expanding the therapeutic applications of our existing products, or (3) resulting in new applications for our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We also may not be able to obtain regulatory approval for any new applications we develop.

### *Litigation and Other Legal Matters*

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The complaint alleged that the Company infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and would infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company manufactured and sold MONOVISC in the United States. On March 7, 2014 Genzyme and the Company filed a joint motion to lift the stay in Genzyme's lawsuit against the Company and to dismiss with prejudice all of Genzyme's claims. On March 10, 2014, the District Court granted the motion to dismiss with prejudice all of Genzyme's claims against the Company and the case was terminated.

We are 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, 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 flows.

## **Results of Operations**

### **Three and Nine Months Ended September 30, 2014 Compared to the Three and Nine Months Ended September 30, 2013**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	2013	Inc/(Dec)	2014	2013	Inc/(Dec)
Product revenue	\$21,975,312	\$17,023,346	29 %	\$57,593,873	\$51,585,242	12 %
Licensing, milestone and contract revenue	80,111	731,092	(89 %)	24,746,497	2,244,584	1002 %
Total revenue	22,055,423	17,754,438	24 %	82,340,370	53,829,826	53 %
Operating expenses:						
Cost of product revenue	5,724,800	5,377,568	6 %	15,418,732	16,530,070	(7 %)
Research & development	1,999,867	1,618,012	24 %	6,160,740	5,029,974	22 %

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

Selling, general & administrative	4,044,538	3,188,669	27 %	11,401,399	10,536,462	8 %
Restructuring credits	-	(196,084 )	(100 %)	-	(442,869 )	(100 %)
Total operating expenses	11,769,205	9,988,165	18 %	32,980,871	31,653,637	4 %
Income from operations	10,286,218	7,766,273	32 %	49,359,499	22,176,189	123 %
Interest income (expense), net	9,937	(32,816 )	(130 %)	16,339	(108,755 )	(115 %)
Income before income taxes	10,296,155	7,733,457	33 %	49,375,838	22,067,434	124 %
Provision for income taxes	4,125,355	2,776,199	49 %	18,872,435	8,147,282	132 %
Net income	\$6,170,800	\$4,957,258	24 %	\$30,503,403	\$13,920,152	119 %
Product gross profit	\$16,250,512	\$11,645,778	40 %	\$42,175,141	\$35,055,172	20 %
Product gross margin	74 %	68 %		73 %	68 %	

*Product Revenue*

Product revenue for the quarter ended September 30, 2014 was \$21,975,312, an increase of 29%, as compared to \$17,023,346 for the quarter ended September 30, 2013. Product revenue for the nine-month period ended September 30, 2014 was \$57,593,873, an increase of 12%, as compared to \$51,585,242 for the nine-month period ended September 30, 2013. For the three months ended September 30, 2014, increases in product revenue from our Orthobiologics, Dermal and Surgical franchises were partially offset by timing related decreases in revenue from our Ophthalmic and Veterinary products. The increase in the nine-month period ended September 30, 2014 from the prior year period was primarily driven by MONOVISC product sales increases both domestically and internationally.

The following table presents product revenue by group for the three and nine-month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Orthobiologics	\$18,899,873	\$12,830,566	\$6,069,307	47 %
Dermal	401,355	267,766	133,589	50 %
Surgical	1,452,946	1,136,248	316,698	28 %
Ophthalmic	366,138	1,425,609	(1,059,471)	(74 %)
Veterinary	855,000	1,363,157	(508,157)	(37 %)
	\$21,975,312	\$17,023,346	\$4,951,966	29 %

	Nine Months Ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Orthobiologics	\$48,750,277	\$40,620,339	\$8,129,938	20 %
Dermal	938,966	1,066,409	(127,443)	(12 %)
Surgical	4,581,496	3,955,134	626,362	16 %
Ophthalmic	938,134	2,818,407	(1,880,273)	(67 %)
Veterinary	2,385,000	3,124,953	(739,953)	(24 %)
	\$57,593,873	\$51,585,242	\$6,008,631	12 %

*Orthobiologics*

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 47% and 20% for the three and nine-month periods ended September 30, 2014, as compared to the same periods in 2013. The growth in the third quarter of 2014 reflected revenue from MONOVISC sales in the U.S. as a result of the product launch in April 2014. We expect orthobiologics product revenue to increase in 2014 as compared to 2013.



*Dermal*

Our dermal franchise consists of advanced wound care products and aesthetic dermal fillers. In July 2014, the Company entered into a new agreement with Medline Industries Inc. to commercialize HYALOMATRIX in the U.S. on an exclusive basis through 2019. For the three and nine month periods ended September 30, 2014, dermal product sales increased 50% and decreased 12%, respectively to \$401,355 and \$938,966, as compared to the same periods in 2013. The fluctuations primarily reflect order timing by our distribution partners. Anika's advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers, with HYALOMATRIX® and HYALOFILL® as the lead products. We expect revenue from our dermal products to grow in the fourth quarter from the third quarter of 2014.

*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 increased 28% and 16% for the three and nine-month periods ended September 30, 2014 to \$1,452,946 and \$4,581,496 respectively, as compared to the same periods in 2013. The year-to-date increase of surgical product revenue was primarily due to strong demand for our HYALOBARRIER® product from our European and Asian partners. For the full year 2014, we expect revenue from our surgical products to increase as compared to 2013.

*Ophthalmic*

Our ophthalmic franchise consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales decreased 74% and 67% to \$366,138 and \$938,134, respectively, for the three and nine-month periods ended September 30, 2014, as compared to the same periods in 2013. The decrease was primarily attributable to Bausch & Lomb (“B&L”) delaying its contractual minimum purchases until the fourth quarter of 2014. We expect the overall ophthalmic revenue to be lower in 2014, as compared to 2013, due to the terms of the current Bausch & Lomb supply agreement. B&L’s current contract expires at the end of this year and will not be renewed. 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 decreased by 37% to \$855,000 and 24% to \$2,385,000 for the three and nine-month periods ended September 30, 2014, respectively, as compared to the same periods in 2013. We expect the overall veterinary revenue to be slightly lower in 2014, as compared to 2013 due to order timing and a slight downward trend in the number of performance horses in the U.S. 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, 2014 was \$80,111 and \$24,746,497, respectively, as compared to \$731,092 and \$2,244,584 for the same periods in 2013. Revenue for the quarter ended June 30, 2014 included a \$5,000,000 milestone payment associated with our U.S. license agreement for MONOVISC. The year to date September 30, 2014 increase in licensing, milestone and contract revenue included a \$17,500,000 milestone payment resulting from the resolution of the patent litigation with Genzyme and the FDA approval of MONOVISC, and the recognition of an approximately \$2,200,000 remaining unamortized upfront payment previously received in December 2011. These payments are related to development obligations under the license agreement. The FDA’s approval of our MONOVISC product during the quarter ended March 31, 2014 completed the delivery of our development obligations under the license agreement, and resulted in the immediate recognition of the \$17.5 million milestone payment, as well as the full recognition of prior deferred revenue in the first quarter of 2014. During the second quarter of 2014, a \$5,000,000 milestone payment associated with the first commercial sale of MONOVISC in the U.S. was earned, received, and recognized as revenue.

*Product gross profit and margin*

Product gross profit and margin for the three and nine-month periods ended September 30, 2014 was \$16,250,512 and \$42,175,141, or 74% and 73%, respectively, of the product revenue. Product gross margin for the three and nine-month periods ended September 30, 2013 was \$11,645,778 and \$35,055,172, or 68% of the product revenue for each period, respectively. The increase in product gross margin for the three and nine-month periods ended September 30, 2014, as compared to the same periods in 2013, is attributable to a more favorable product mix, materials cost reduction, and continued efficiency gains at our Bedford, Massachusetts manufacturing facility. This quarter's product gross margin may not be indicative of the rest of the year due to dynamics including the future mix of our product sales and other factors.

#### *Research and development*

Research and development expenses for the three and nine-month periods ended September 30, 2014 were \$1,999,867 and \$6,160,740, or 9% and 8% of total revenue, respectively. This primarily reflects the completion of patient follow-up activities of our phase III Cingal clinical trial during the first nine months of 2014, as compared to trial start-up activities in the same periods last year. Research and development spending is expected to increase in future quarters as we further develop new products based on our existing technology assets.

#### *Selling, general and administrative*

Selling, general and administrative ("SG&A") expenses for the three and nine-month periods ended September 30, 2014 were \$4,044,538 and \$11,401,399, or, representing 19% and 14% of total revenue, respectively. SG&A expenses increased for both the three and nine-month periods ending September 30, 2014, as compared to the same periods in 2013, primarily as a result of increases in personnel related costs, external professional fees, and corporate governance costs. Included in the first quarter of 2013 were certain non-recurring external professional fees and personnel costs. We expect general and administrative expenses to increase in 2014, as compared to 2013, reflective of the support required to grow our business both domestically and internationally.

*Income taxes*

Provisions for income taxes were \$4,125,355 and \$18,872,435 for the three and nine-month periods ended September 30, 2014, based on effective tax rates of 40% and 38%, respectively. Provisions for income taxes were \$2,776,199 and \$8,147,282 for the three and nine-month periods ended September 30, 2013, respectively, based on effective tax rates of 36% and 37%, respectively. The increase in income taxes over the three-month period ended September 30, 2014 was primarily due to increased net income. The increase in income taxes over the nine-month period ended September 30, 2014 was primarily due to increased net income, which reflected \$24,652,778 in milestone and contract revenue associated with our U.S. license agreement for MONOVISC. The increase in the effective tax rate for each of the periods ended 2014, as compared to the same periods ended in 2013, was driven primarily by the unavailability of the federal R&D tax credit in 2014, due to its expiration on December 31, 2013, and a relative decrease to our estimated production activities deduction.

The Company files income tax returns in the U.S. 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. Our 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. Our filings from 2009 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. We have 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, we have not recorded a valuation allowance at September 30, 2014 or December 31, 2013.

*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 \$91.8 million and \$63.3 million at September 30, 2014 and December 31, 2013, respectively. Working capital totaled approximately \$122.2 million at September 30, 2014 and \$85.3 million at December 31, 2013. The Company believes it has adequate financial resources to support its business for the next twelve months.

Cash provided by operating activities was \$25,222,372 for the nine months ended September 30, 2014, as compared to cash provided by operating activities of \$17,159,199 for the same period in the prior year. This increase in cash provided by operations was due primarily to a total of \$22.5 million milestone payments received under the Mitek

MONOVISC Agreement. This cash inflow is partially offset by an increase in inventory due to anticipated future sales demand.

Cash used in investing activities was \$20,919,301 for the nine months ended September 30, 2014 as compared to cash provided by investing activities of \$295,062 for the same period in 2013. The increase in cash used in investing activities is primarily the result of the purchase of approximately \$20.0 million in marketable securities during the third quarter as well as higher capital expenditures in 2014 as compared to the same period in 2013, which included the proceeds received from the sale of property and equipment in the prior year period relating to our reorganization of Anika S.r.l. in the beginning of 2013.

Cash provided by financing activities was \$4,267,102 for the nine months ended September 30, 2014, as compared to cash provided by financing activities of \$2,496,830 for the same period in 2013. The increase in cash provided by financing activities in the current year's period is attributable to the increased tax benefits received in regards to employees' exercise of stock options during the first nine months of 2014, partially offset by minimum tax withholdings on share-based awards.

#### *Critical Accounting Estimates*

During the nine months ended September 30, 2014, the Company received FDA approval of MONOVISC and the patent litigation related to MONOVISC was also resolved. As a result, the Company shortened the estimate of the performance period related to the Mitek MONOVISC Agreement. There were no other significant changes in our critical accounting estimates during the nine months ended September 30, 2014, as compared to the 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, 2013.

### ***Recent Accounting Pronouncements***

In June 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-12, “Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period,” which requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. Thus, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The new guidance is effective for the Company beginning January 1, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this new standard on its financial statements.

In May 2014, the FASB issued 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. ASU 2014-09 is effective retrospectively for annual or interim reporting periods beginning after December 15, 2016, with early application not permitted. The Company is currently evaluating the impact of this new standard on its financial statements.

In April 2014, the FASB issued ASU No. 2014-08, "Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity." ASU 2014-08 provides a narrower definition of discontinued operations than under existing U.S. GAAP. ASU 2014-08 requires that only a disposal of a component of an entity, or a group of components of an entity, that represents a strategic shift that has, or will have, a major effect on the reporting entity's operations and financial results should be reported in the financial statements as discontinued operations. ASU 2014-08 also provides guidance on the financial statement presentations and disclosures of discontinued operations. ASU 2014-08 is effective prospectively for disposals (or classifications as held for disposal) of components of an entity that occur in annual or interim periods beginning after December 15, 2014. The Company does not expect the adoption of ASU 2014-08 to have a material impact on the consolidated financial statements.

### ***Contractual Obligations and Other Commercial Commitments***

We have had no material changes outside the ordinary course to our contractual obligations disclosed in our Annual Report on Form 10-K for the period ended December 31, 2013.

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***

The Company does 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**

There have been no material changes to our market risks since the date of our Annual Report on Form 10-K for the year ended December 31, 2013.

As of September 30, 2014, we did not utilize any derivative financial or commodity instruments for which fair value disclosure would be required under ASC 825, *Financial Instruments*, or ASC 815, *Derivatives and Hedging*. Our marketable securities investments consist of money market funds primarily invested in certificates of deposit, commercial paper, U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations that are carried on our books at fair market value.

*Primary Market Risk Exposures*

Our primary market risk exposure is in the area of currency rate risk. We have three supplier contracts denominated in foreign currencies. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of changes in currency exchange rates for these supplier contracts on our financial statements was immaterial for the three months ended September 30, 2014. The impact of exchange rates related to the consolidation of the balance sheet amounts for our Anika S.r.l. subsidiary resulted in an unfavorable currency translation adjustment of \$1,896,823 during the first nine months of 2014.

Our investment portfolio of cash equivalents and marketable securities is subject to interest rate fluctuations, changes in credit quality of the issuer or other factors.

**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 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 Securities and Exchange Commission 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 September 30, 2014 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**

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The complaint alleged that the Company infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and would infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company manufactured and sold MONOVISC in the United States. On March 7, 2014, Genzyme and the Company filed a joint motion to lift the stay in Genzyme's lawsuit against the Company and to dismiss with prejudice all of Genzyme's claims. On March 10, 2014, the District Court granted the motion to dismiss with prejudice all of Genzyme's claims against the Company and the case was terminated.

We are 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, 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.

### **ITEM 1A. RISK FACTORS**

To our knowledge there have been no material changes to the risk factors described in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013. In addition to the other information set forth in this report, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, 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 5. OTHER INFORMATION**

On November 5, 2014, our Board of Directors approved a form of indemnification agreement for our directors and authorized the Company to enter into such an agreement with each of our directors. Under the terms of the agreement, consistent with the provisions of our Articles of Incorporation, Bylaws and applicable law, the Company agrees to indemnify each director, to the maximum extent permitted by the laws of the Commonwealth of Massachusetts, from claims and losses arising from their service as a director. Subject to certain procedures outlined in the agreement, we are required to advance expenses incurred as a result of any such proceeding as to which a director could be indemnified. The agreement provides procedures for the determination of a person's right to receive indemnification consistent with applicable laws. We anticipate that we will enter into substantially similar agreements with any new directors. The form of indemnification agreement is attached hereto as Exhibit 10.1 and incorporated by reference

herein. The foregoing summary of the indemnification agreement is qualified in its entirety by the text of the Exhibit.

## ITEM 6. EXHIBITS

### Exhibit No. Description

- \*10.1 Form of Director Indemnification Agreement
- (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

The following materials from Anika Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, as filed with the SEC on November 5, 2014, formatted in XBRL (eXtensible Business Reporting Language), as follows:

- i. Condensed Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013
- ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2014 and September 30, 2013 (unaudited)
- iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 and September 30, 2013 (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 5, 2014 By: /s/ SYLVIA CHEUNG

Sylvia Cheung

*Chief Financial Officer*

(Authorized Officer and Principal Financial Officer)