

ANIKA THERAPEUTICS INC  
Form 10-Q  
November 08, 2012

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended September 30, 2012

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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Commission File Number 000-21326

Anika Therapeutics, Inc.  
(Exact Name of Registrant as Specified in Its Charter)

Massachusetts  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

01730  
(Zip Code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

Large accelerated filer <input type="radio"/>	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="radio"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="radio"/>
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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 November 1, 2012 there were 13,812,747 outstanding shares of Common Stock, par value \$.01 per share.

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PART I: FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$39,855,856	\$35,777,222
Accounts receivable, net of reserves of \$464,442 and \$334,473 at September 30, 2012 and December 31, 2011, respectively	16,343,600	17,307,786
Inventories	8,932,492	7,302,483
Current portion deferred income taxes	1,918,926	1,918,926
Prepaid expenses and other	1,351,403	1,831,127
Total current assets	68,402,277	64,137,544
Property and equipment, at cost	52,141,685	50,850,630
Less: accumulated depreciation	(16,204,216 )	(14,380,752 )
	35,937,469	36,469,878
Long-term deposits and other	249,381	205,042
Intangible assets, net	21,464,089	23,148,563
Goodwill	8,818,920	8,883,407
Total Assets	\$134,872,136	\$132,844,434
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,907,564	\$4,299,680
Accrued expenses	4,389,002	5,321,594
Deferred revenue	2,866,667	2,866,667
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	1,391,694	450,482
Total current liabilities	12,154,927	14,538,423
Other long-term liabilities	1,539,198	1,548,652
Long-term deferred revenue	2,869,440	5,019,440
Deferred tax liability	6,435,148	7,375,141
Long-term debt	8,400,000	9,600,000
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, 2012 and December 31, 2011, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 13,804,975 and 13,630,607 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	138,049	136,305
Additional paid-in-capital	65,142,128	63,441,433
Accumulated currency translation adjustment	(3,353,212 )	(3,067,181 )
Retained earnings	41,546,458	34,252,221
Total stockholders' equity	103,473,423	94,762,778
Total Liabilities and Stockholders' Equity	\$134,872,136	\$132,844,434

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,	
	2012	2011	2012	2011
Product revenue	\$ 14,055,440	\$ 17,756,000	\$ 46,551,045	\$ 44,230,840
Licensing, milestone and contract revenue	711,171	699,817	2,200,995	2,103,508
Total revenue	14,766,611	18,455,817	48,752,040	46,334,348
<b>Operating expenses:</b>				
Cost of product revenue	7,221,028	7,394,922	21,718,735	19,655,288
Research & development	1,217,086	1,531,355	4,048,359	4,638,175
Selling, general & administrative	3,601,737	4,712,178	11,061,256	12,989,268
Total operating expenses	12,039,851	13,638,455	36,828,350	37,282,731
Income from operations	2,726,760	4,817,362	11,923,690	9,051,617
Interest income (expense), net	(45,161 )	(46,269 )	(145,493 )	(132,471 )
Income before income taxes	2,681,599	4,771,093	11,778,197	8,919,146
Provision for income taxes	1,036,349	1,794,575	4,483,960	3,335,576
Net income	\$ 1,645,250	\$ 2,976,518	\$ 7,294,237	\$ 5,583,570
<b>Basic net income per share:</b>				
Net income	\$0.12	\$0.23	\$0.55	\$0.44
Basic weighted average common shares outstanding	13,287,463	12,817,910	13,237,629	12,744,471
<b>Diluted net income per share:</b>				
Net income	\$0.11	\$0.22	\$0.51	\$0.41
Diluted weighted average common shares outstanding	14,459,154	13,765,533	14,357,791	13,729,835
Net income	\$ 1,645,250	\$ 2,976,518	\$ 7,294,237	\$ 5,583,570
<b>Other comprehensive income</b>				
Foreign currency translation adjustment	557,712	(1,576,131 )	(286,031 )	768,731
Comprehensive income	\$ 2,202,962	\$ 1,400,387	\$ 7,008,206	\$ 6,352,301

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,	
	2012	2011
Cash flows from operating activities:		
Net income	\$7,294,237	\$5,583,570
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,364,432	2,943,295
Stock-based compensation expense	914,003	901,619
Deferred income taxes	(1,012,571 )	1,116,456
Provision for doubtful accounts	135,353	-
Provision for inventory	790,379	642,120
Tax benefit from exercise of stock options	(456,796 )	-
Changes in operating assets and liabilities:		
Accounts receivable	716,874	(2,721,155 )
Inventories	(2,433,367 )	516,647
Prepaid expenses, other current and long-term assets	429,718	454,804
Long-term deposits and other	25,496	162,997
Accounts payable	(2,399,999 )	(6,252,826 )
Accrued expenses	(873,153 )	51,152
Deferred revenue	(2,150,000 )	(1,884,307 )
Income taxes payable	1,398,008	1,368,665
Other long-term liabilities	(6,318 )	(17,224 )
Net cash provided by operating activities	5,736,296	2,865,813
Cash flows from investing activities:		
Purchase of property and equipment	(1,292,487 )	(953,952 )
Net cash used in investing activities	(1,292,487 )	(953,952 )
Cash flows from financing activities:		
Principal payments on debt	(1,200,000 )	(1,200,000 )
Proceeds from exercise of stock options	331,639	151,770
Tax benefit from exercise of stock options	456,796	-
Net cash used in financing activities	(411,565 )	(1,048,230 )
Exchange rate impact on cash	46,390	(16,899 )
Increase in cash and cash equivalents	4,078,634	846,732
Cash and cash equivalents at beginning of period	35,777,222	28,201,932
Cash and cash equivalents at end of period	\$39,855,856	\$29,048,664

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. (together with its subsidiaries, “Anika,” the “Company,” “we,” “us,” or “our”) develops, manufacture 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 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, 2012 and the results of its operations for the three and nine months ended September 30, 2012 and 2011 and cash flows for the nine months ended September 30, 2012 and 2011.

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, 2011. There have been no changes in our significant accounting policies for the three and nine months ended September 30, 2012 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012. Certain prior period amounts have been reclassified to conform to the current period presentation. There was no impact on operating income.

3. Recent Accounting Pronouncements Issued or Adopted

On May 12, 2011, the Financial Accounting Standards Board (“FASB”), together with the International Accounting Standards Board, jointly issued Accounting Standards Update (“ASU”) 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. The provisions of ASU 2011-04 give fair value the same meaning between U.S. GAAP and International Financial Reporting Standards, and improve consistency of disclosures relating to fair value. For public entities, the amendments are effective during interim and

annual periods beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The amendments in this ASU require all non-owner changes in stockholders' equity to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. For public entities, the amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In September 2011, the FASB issued ASU 2011-08, Intangibles – Goodwill and Other. This ASU's objective is to simplify the process of performing impairment testing for Goodwill. With this update, a company is allowed to first assess qualitative factors to determine if it is more likely than not (greater than 50%) that the fair value of its goodwill and intangible assets is less than the carrying amount. This step is done prior to performing the two-step goodwill impairment testing, as prescribed by Topic 350. This ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations or cash flows.



In July 2012, the FASB issued ASU 2012-02, Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This amendment is an update of ASU 2011-08, specifically for consistency of approach in assessing impairment for Indefinite-Lived assets and permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, Intangibles - Goodwill and Other - General Intangibles Other than Goodwill. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. This ASU is effective for annual and interim periods beginning after September 15, 2012. Early adoption is permitted. The adoption of this amendment will not have a material impact on our consolidated financial position, results of operations or cash flows.

#### 4. Fair Value Measurements

We measure certain assets and liabilities, such as fixed income investments, at fair value based upon exit price, representing the amount that would be received on the sale of an asset or paid to transfer a liability, as the case may be, in an orderly transaction between market participants. As such, fair value may be based on assumptions that market participants would use in pricing an asset or liability. To increase the comparability of fair value measurements, the following hierarchical levels of inputs to valuation methodologies are used:

Level 1 – Valuation is based upon quoted prices for identical instruments traded in active markets. Level 1 instruments include securities traded on active exchange markets, such as the New York Stock Exchange.

Level 2 – Valuation is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market.

Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect our own estimates of assumptions market participants would use in pricing the asset or liability.

The following table summarizes our assets measured and recorded at fair value on a recurring basis, by level, within the fair value hierarchy:

	September 30, 2012			Total
	Level 1	Level 2	Level 3	
Assets measured at fair value:				
Cash equivalents - money market accounts	\$20,263,766	\$-	\$-	\$20,263,766
	December 31, 2011			Total
	Level 1	Level 2	Level 3	
Assets measured at fair value:				
Cash equivalents - money market accounts	\$20,263,766	\$-	\$-	\$20,263,766

## 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 months ended September 30, 2012 and 2011, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,	
	2012	2011
Risk free interest rate	0.63%	N/A
Expected volatility	57.60%	N/A
Expected lives (years)	4	N/A
Expected dividend yield	0.00%	N/A

  

	Nine Months Ended September 30,	
	2012	2011
Risk free interest rate	0.63% - 0.64%	1.19% - 1.51%
Expected volatility	57.60%	57.60%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

The Company recorded \$280,930 and \$914,003 of share-based compensation expense for the three and nine months ended September 30, 2012, respectively, for equity compensation awards. The Company recorded \$319,312 and \$901,619 of share-based compensation expense for the three and nine months ended September 30, 2011. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the respective employees.

There were 75,000 stock options granted under the Second Amended and Restated 2003 Stock Option and Incentive Plan (the "Plan") during the three months ended September 30, 2012. There were 194,000 stock options granted under the Plan during the nine months ended September 30, 2012. There were no restricted stock units ("RSUs") granted to members of the Company's Board of Directors during the three months ended September 30, 2012. There were 16,480 RSUs granted to members of the Company's Board of Directors under the Plan during the nine months ended September 30, 2012. The stock options and RSUs granted to employees and directors become exercisable or vest ratably over four years from the date of grant.

As of September 30, 2012, there was approximately \$2.6 million of total unrecognized compensation cost related to non-vested stock options, stock appreciation rights ("SARs"), and restricted stock awards ("RSAs") granted under the Company's incentive plans. This cost is expected to be recognized over a weighted-average period of approximately 2.5 years.

The total intrinsic value of stock options and SARs exercised during the nine-month periods ended September 30, 2012 and 2011 was \$1,643,502 and \$628,007 respectively. Cash received from the exercise of stock options during the three and nine-month periods ended September 30, 2012 was \$184,606 and \$331,639, respectively. Cash received from the exercise of stock options during the nine-month period ended September 30, 2011 was \$151,770.

There were approximately 1.9 million options and SARs outstanding under the Company's incentive plans at September 30, 2012 with a weighted-average exercise price of \$8.20 per share, an aggregate intrinsic value of approximately \$13.3 million, and a weighted-average remaining contractual term of 4.77 years.

None of the options or SARs outstanding at September 30, 2012 or 2011, 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 contain service or performance conditions and generally become exercisable ratably over one to four years and have a ten year contractual term.

## 6. Earnings Per Share

The Company reports earnings per share in accordance with Accounting Standards Codification (“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 months ended September 30, 2012 and 2011 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Shares used in the calculation of Basic earnings per share	13,287,463	12,817,910	13,237,629	12,744,471
Effect of dilutive securities:				
Stock options, SARs, RSAs, and shares held in escrow	1,171,691	947,623	1,120,162	985,364
Diluted shares used in the calculation of earnings per share	14,459,154	13,765,533	14,357,791	13,729,835

In connection with the acquisition of Anika Therapeutics S.r.l. (“Anika S.r.l.”) on December 30, 2009, the Company issued 1,981,192 shares of its common stock of which 500,000 of these shares remain in escrow at September 30, 2012. These 500,000 shares are included in the diluted potential common shares but are excluded from the basic earnings per share calculation. See Note 10 for additional information relative to this item.

Equity awards of 133,064 and 104,187 shares were outstanding for the three and nine months ended September 30, 2012, respectively, but 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 1,674,331 and 1,057,096 shares were outstanding for the three and nine months ended September 30, 2011, respectively, but 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, 2012	December 31, 2011
Raw materials	\$5,655,726	\$4,091,366
Work-in-process	1,450,843	1,503,565
Finished goods	1,825,923	1,707,552
Total	\$8,932,492	\$7,302,483

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 S.r.l., the Company acquired various intangible assets and goodwill. The Company evaluated the various intangibles and related cash flows from these intangible assets, as well as the useful lives and amortization methods related to these intangibles. The in-process research and development 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, 2012 and December 31, 2011 consist of the following:

	September 30, 2012			December 31, 2011		Useful Life
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	
Developed technology	\$ 16,700,000	\$ (1,618,177)	\$ (2,694,831)	\$ 12,386,992	\$ 13,228,351	15
In-process research & development	6,698,000	(793,422 )	-	5,904,578	5,955,066	Indefinite
Distributor relationships	4,700,000	(484,422 )	(2,318,568)	1,897,010	2,547,842	5
Patents	1,000,000	(103,070 )	(154,160 )	742,770	790,555	16
Eleveess trade name	1,000,000	-	(467,261 )	532,739	626,749	9
Total	\$ 30,098,000	\$ (2,999,091)	\$ (5,634,820)	\$ 21,464,089	\$ 23,148,563	

The aggregate amortization expense related to intangible assets was \$494,301 and \$547,448 for the three months ended September 30, 2012 and 2011, respectively. The aggregate amortization expense for the nine months ended September 30, 2012 and 2011 was \$1,517,285 and \$1,629,264 respectively.

Changes in the carrying value of goodwill for the three and nine months ended September 30, 2012 were as follows:

	For the three months ended: September 30, 2012	For the nine months ended: September 30, 2012
Balance, beginning	\$8,627,518	\$8,883,407
Effect of foreign currency adjustments	191,402	(64,487 )
Balance, ending	\$8,818,920	\$8,818,920

#### 9. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2012	December 31, 2011
Payroll and benefits	\$2,172,045	\$2,498,492
Professional fees	452,140	1,052,058
Research grants	1,179,007	1,313,280
Other	585,810	457,764
Total	\$4,389,002	\$5,321,594

#### 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 (“Genzyme”) 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 alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. On April 26, 2011, Genzyme filed a motion to add its newly-issued U.S. Patent No. 7,931,030 to this litigation and also filed a separate new complaint in the District of Massachusetts alleging that the Company's manufacture and sale of MONOVISC in the United States will infringe that patent. On May 23, 2011, the Court entered orders permitting Genzyme to file its supplemental complaint adding its newly-issued U.S. Patent No. 7,931,030 to this litigation and requiring Genzyme to withdraw its separately filed complaint. On July 14, 2011, the Company filed an answer to the supplemental complaint, denying liability. On May 10, 2012, Genzyme dismissed its claims of infringement of U.S. Patent No. 5,399,351 and is no longer asserting that patent against the Company. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with Depuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product. On September 19, 2012, Genzyme and the Company jointly requested that the Court stay Genzyme’s lawsuit against the Company pending the full resolution of the Seikagaku/Zimmer lawsuit, including through any appeal of the judgment entered in that lawsuit. The District Court granted the motion on September 28, 2012.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging, discovered by the Company. We settled the matter related to this dispute with Medtronic in August, 2012. As this error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A., we have made claims against Fidia for indemnification for Anika’s losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the Anika S.r.l. acquisition. Management has assessed Fidia’s claim and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for any related loss contingency.

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.

#### 11. Long-term Debt

On January 31, 2008, the Company entered into an unsecured Credit Agreement with Bank of America. As of September 30, 2012, the Company had an outstanding debt balance of \$10,000,000, at an interest rate of 1.64%. The interest rate payable on our debt is determined, at the Company’s option, based on LIBOR plus 1.25%, or the lender’s prime rate.

ASC 825, Financial Instruments, requires disclosure about the fair value of financial instruments in interim as well as in annual financial statements. The carrying value of our debt instrument was \$10,000,000 and \$11,200,000 at September 30, 2012 and December 31, 2011, respectively, of which \$1,600,000 was recorded as current at each date. The estimated fair value of our debt, which is a Level 2 instrument for fair value measurement purposes, approximated book value at September 30, 2012 and December 31, 2011, respectively.



12. Income Taxes

Provisions for income taxes were \$1,036,349 and \$4,483,960 for the three and nine-month periods ended September 30, 2012, respectively, based on effective tax rates of 38.6 % and 38.1 %. Provisions for income taxes were \$1,794,575 and \$3,335,576 for the three and nine-month periods ended September 30, 2011, respectively, based on effective tax rates of 37.6% and 37.4%. The increase in the effective tax rates for the periods ended 2012, as compared to the same periods in the previous year, are primarily due to lower tax credits anticipated in the current year, including the federal R&D credit which expired with the 2011 tax year, combined with larger losses experienced by Anika S.r.l. as compared to the same periods in 2011.

In the normal course of business, Anika and its subsidiaries may be periodically examined by various taxing authorities. We file income tax returns in the U.S. federal jurisdiction, 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 2009 through 2011 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state purposes. The 2009 through 2011 tax years 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 and its investment tax credit carryforward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that 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, 2012 or December 31, 2011, respectively.

### 13. Related Party

In connection with our acquisition of Anika S.r.l. on December 30, 2009, Fidia Farmaceutici S.p.A. (“Fidia”) acquired ownership of 1,981,192 shares of the Company's common stock, of which 500,000 shares remain in escrow at September 30, 2012. As of September 30, 2012, Fidia owns approximately 14.4% of the outstanding shares of the Company.

As part of the acquisition, the Company, primarily through Anika S.r.l., entered into a series of operating agreements with Fidia as follows:

Agreement Type	Description	Term in Years
Lease	Rent of space in Abano Terme, Italy	Six
Finished goods supply	Manufacture and supply of goods	Three
Raw material supply	Hyaluronic acid powder	Five
Accounts receivable management	Collection of trade receivables outstanding as of December 30, 2009	Two
Marketing and Promotion	Promote Anika S.r.l. products in Italy through Fidia sales force	Three

Historically, Anika S.r.l. has relied on Fidia, its former parent company, for several functional activities. In connection with the purchase of Anika S.r.l., the Company has negotiated a lease for approximately 26,000 square feet of office, laboratory and warehouse space in Abano Terme, Italy, and a finished goods supply agreement. The Marketing and Promotion agreement was terminated during the first quarter of 2012. We had a net payable to Fidia for past products and services of approximately \$256,000 at September 30, 2012.

### 14. 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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Orthobiologics	\$9,242,783	\$10,377,222	\$30,262,991	\$28,177,115
Dermal	376,251	947,122	1,033,302	2,335,881
Ophthalmic	1,891,433	4,562,574	8,515,160	8,045,203
Surgical	1,426,273	1,068,522	3,874,405	3,748,277
Veterinary	1,118,700	800,560	2,865,187	1,924,364
	\$14,055,440	\$17,756,000	\$46,551,045	\$44,230,840



Product revenue by geographic location in total and as a percentage of total product revenue, for the three and nine months ended September 30, 2012 and 2011 are as follows (Prior period numbers have been reclassified to conform to the current period presentaion):

Geographic Location:	Three Months Ended September 30,					
	2012			2011		
	Revenue	Percentage of Revenue		Revenue	Percentage of Revenue	
United States	\$11,911,946	85	%	\$13,233,998	75	%
Europe	1,069,661	7	%	2,512,690	14	%
Other	1,073,833	8	%	2,009,312	11	%
Total	\$14,055,440	100	%	\$17,756,000	100	%

Geographic Location:	Nine Months Ended September 30,					
	2012			2011		
	Revenue	Percentage of Revenue		Revenue	Percentage of Revenue	
United States	\$38,317,667	82	%	\$33,170,393	75	%
Europe	3,937,427	9	%	6,887,323	16	%
Other	4,295,951	9	%	4,173,124	9	%
Total	\$46,551,045	100	%	\$44,230,840	100	%

ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND  
2. RESULTS 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 and efficiency gains and work-in-process manufacturing operations;
    - The timing, scope and rate of patient enrollment for clinical trials;
    - The development of possible new products;
  - Our ability to achieve or maintain compliance with laws and regulations;
- The timing of and/or receipt of the Food and Drug Administration, 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 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 or supply agreements or 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 current strategy, including our corporate objectives and research and development and collaboration opportunities;
- Our and Bausch & Lomb's performance under the non-exclusive supply agreement for AMVISC® and AMVISC® Plus ophthalmic viscoelastic products that expires on December 31, 2014, and our expectations regarding revenue generated from ophthalmic products;
- Our ability to commercialize AnikaVisc and AnikaVisc Plus, and our expectations regarding such commercialization and the potential revenue generated thereby;
- Our expectations regarding our joint health products, including expectations regarding new products, expanded uses of existing products, new distribution and revenue growth;
- Our intention to increase market share for joint health products in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;
- Our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals and commercial launches;

- Our expectations regarding revenue from sales of HYVISC®;
- Our ability to identify a new distribution partner for HYDRELLE™ in the United States and the impact this may have on future sales of this product;

- Our ability to license our aesthetics product to new distribution partners outside of the United States; our ability, and the ability of our distribution partners, to market our aesthetic dermatology product; and our expectations regarding the distribution and sales of our ELEVESSTM product and the timing thereof;
- Our ability to achieve operational efficiencies and higher-rate manufacturing abilities from the transfer of our manufacturing capabilities to the Bedford Facility;
  - Our expectations regarding our ability to ship the delayed Orthovisc orders;
  - Our expectations regarding development of aesthetics product line extensions;
    - Our expectations regarding product gross margin;
- Our expectations regarding our U.S. MONOVISC® trials and the results of the related premarket approval (“PMA”) filing with the FDA, including the escalation of the appeal process with the FDA and the FDA’s review of the additional information requested from us in order to pass judgment on the appeal, and the likelihood of our obtaining such approval and/or the anticipated timing thereof;
- Our expectations regarding the commencement of a clinical trial for Hyalograft C Autograft and CINGAL™, including the expense associated therewith, and our ability to obtain regulatory approvals for these products;
- 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 expectation regarding the adequacy of such cash;
  - Our expectation for capital expenditures spending and future amounts of interest income and expense;
  - Possible negotiations or re-negotiations with existing or new distribution or collaboration partners;
    - Our ability to remain in compliance with debt covenants;
  - 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 abilities to successfully manage Anika S.r.l.’s operations from one with losses, into a company generating 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 abilities to effectively prioritize the many research and development projects underway;
- Our ability to obtain U.S. approval for the 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;
- Our ability to satisfactorily resolve the dispute with Fidia Farmaceutici S.p.A regarding Merogel Injectable; and

- Our ability to successfully defend the Company against lawsuits and claims, including the Genzyme lawsuit, 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,” “i  
“seek,” “designed,” “develop,” “would,” “future,” “can,” “could,” and other expressions that are predictions of or indicate  
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, 2011. 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, 2011 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.

In October 2011, we received additional orders from Bausch & Lomb (“B&L”) for ophthalmic products to be delivered in the first half of 2012. Effective January 1, 2012, the parties agreed to a new three year contract for Anika to continue to supply these products to B&L as a second supplier with additional committed volumes for 2012, and reduced annual commitments in 2013 and 2014. During the first half of 2012, we received all FDA approvals required to manufacture our aseptic products in our Bedford facility, including AmVisc and AmVisc Plus.

Anika S.r.l., our Italian subsidiary, has over 20 products currently commercialized, primarily in Europe. These products are all made from HA, and are 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 patents. With the 2009 acquisition of Anika S.r.l., the Company is offering therapeutic products in the following areas:

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

During the first quarter of 2012, the Company entered into an agreement with a new distributor for Anika S.r.l.’s products in the Italian market, which consist of orthopedic and advanced wound care products. The transition to the new distributor resulted in a decline in Italian revenue during the nine-month period ended September 30, 2012, as compared to the same period in the prior year. Historically, a significant portion of the Company’s accounts receivable arising from product sales within Italy by Anika S.r.l. were due from public hospitals and other government-funded healthcare agencies. As of September 30, 2012, the Company’s accounts receivable from all Italian customers totaled approximately \$1.4 million of which public hospital and agency receivables were approximately \$0.4 million.

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, 2011, 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 relative to our existing and new products. Our development focus includes products for new indications, chemically modified formulations of HA designed for longer residence time in the body, and other development activities. Our investment in R&D has been important over the years, and varies considerably depending on the number and size of clinical trials and studies underway. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

With the acquisition of Anika S.r.l., we have enhanced both our research and development capabilities and our pipeline of candidate products. Anika S.r.l. has research and development programs for new products including Hyalobone, a bone tissue filler, and Hyalospine, an adhesion prevention gel for use after spinal surgery.

Our first next generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary cross-linked HA-technology. We received Conformité Européenne (“CE”) Mark approval for the MONOVISC product in October 2007, and began sales in Europe during the second quarter of 2008, following a small, post-marketing clinical study. In the U.S., we filed the final module of our MONOVISC PMA containing the clinical data in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter, which is the FDA’s mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by the FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The FDA denied our request for an Orthopedic Advisory Panel review of the product, and we have now moved to the next level in the appeal process structure of the FDA. On June 12, 2012, the Company attended a supervisory appeal meeting with the Chief Scientific Officer of the Center for Devices and Radiological Health (CDRH), a branch of the FDA, to address concerns related to the non-approvable letter issued by the FDA for the Company’s Monovisc PMA. The FDA requested additional information in order to pass judgement on the appeal. The Company has submitted that information, and was promised a timely review and decision by the FDA. We continue to believe in MONOVISC and the strength of our data, and that MONOVISC should receive FDA approval. Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule to provide broad pain relief for a longer period of time. We filed a CE Mark application in the European Union for CINGAL in November 2011. We expect to commence a clinical trial in early 2013 to generate the data required to gain CE Mark approval for CINGAL.

#### Contracts

As disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, Anika has been a contract manufacturer for B&L for over 20 years. Anika’s Supply Agreement with B&L expired on December 31, 2010. Effective January 1, 2011, we entered into a non-exclusive, two year contract with B&L intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, formerly affiliated low-cost supplier to B&L. Effective January 1, 2012, the parties agreed to a new three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes in 2012, and a lower committed volume for 2013 and 2014. B&L accounted for approximately 17%, or \$7.7 million, of our product revenue for the nine-month period ended September 30, 2012, as compared to approximately 16%, or \$6.9 million of our product revenue for the nine-month period ended September 30, 2011. We continue to expect the full-year product revenue derived from sales to B&L to be lower in 2012 compared to 2011.

#### Litigation and Other Legal Matters

On July 7, 2010, Genzyme Corporation (“Genzyme”) 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 alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. On April 26, 2011, Genzyme filed a motion to add its newly-issued U.S. Patent No. 7,931,030 to this litigation and also filed a separate new complaint in the District of Massachusetts alleging that the Company’s manufacture and sale of MONOVISC in the United States will infringe that patent. On May 23, 2011, the Court entered orders permitting Genzyme to file its supplemental complaint adding its newly-issued U.S. Patent No. 7,931,030 to this litigation and requiring Genzyme to withdraw its separately filed complaint. On July 14, 2011, the Company filed an answer to the supplemental complaint, denying liability. On May 10, 2012, Genzyme dismissed its claims of infringement of U.S. Patent No. 5,399,351 and is no longer asserting that patent against the Company. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable

claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with Depuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product. On September 19, 2012, Genzyme and the Company jointly requested that the Court stay Genzyme's lawsuit against the Company pending the full resolution of the Seikagaku/Zimmer lawsuit, including through any appeal of the judgment entered in that lawsuit. The District Court granted the motion on September 28, 2012.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging, discovered by the Company. We have settled the matter related to this dispute with Medtronic. As this error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A., we have made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the Anika S.r.l. acquisition. Management has assessed Fidia's claim and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for any related loss contingency.

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.

## Results of Operations

Three and Nine Months Ended September 30, 2012 Compared to the Three and Nine Months Ended September 30, 2011

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Inc/(Dec)	2012	2011	Inc/(Dec)
Product revenue	\$ 14,055,440	\$ 17,756,000	-20.8 %	\$ 46,551,045	\$ 44,230,840	5.2 %
Licensing, milestone and contract revenue	711,171	699,817	1.6 %	2,200,995	2,103,508	4.6 %
Total revenue	14,766,611	18,455,817	-20.0 %	48,752,040	46,334,348	5.2 %
Operating expenses:						
Cost of product revenue	7,221,028	7,394,922	-2.4 %	21,718,735	19,655,288	10.5 %
Research & development	1,217,086	1,531,355	-20.5 %	4,048,359	4,638,175	-12.7 %
Selling, general & administrative	3,601,737	4,712,178	-23.6 %	11,061,256	12,989,268	-14.8 %
Total operating expenses	12,039,851	13,638,455	-11.7 %	36,828,350	37,282,731	-1.2 %
Income from operations	2,726,760	4,817,362	-43.4 %	11,923,690	9,051,617	31.7 %
Interest income (expense), net	(45,161 )	(46,269 )	-2.4 %	(145,493 )	(132,471 )	9.8 %
Income before income taxes	2,681,599	4,771,093	-43.8 %	11,778,197	8,919,146	32.1 %
Provision for income taxes	1,036,349	1,794,575	-42.3 %	4,483,960	3,335,576	34.4 %
Net income	\$ 1,645,250	\$ 2,976,518	-44.7 %	\$ 7,294,237	\$ 5,583,570	30.6 %
Product gross margin	6,834,412	10,361,078	-34.0 %	24,832,310	24,575,552	1.0 %
Product gross margin	49 %	58 %		53 %	56 %	

## Product Revenue

Product revenue for the quarter ended September 30, 2012 was \$14,055,440, a decrease of 21%, as compared to \$17,756,000 for the quarter ended September 30, 2011. Product revenue for the nine months ended September 30, 2012 was \$46,551,045, an increase of 5%, as compared to \$44,230,840 for the nine months ended September 30, 2011. The third quarter decrease was primarily driven by a temporary scale-up issue at our Bedford manufacturing facility that prevented the Company from filling all of its orders for ORTHOVISC during the third quarter of 2012, combined with the anticipated year-over-year reduction in our ophthalmic franchise sales. The scale-up issue has been resolved and the delayed ORTHOVISC orders are expected to be filled in the fourth quarter of 2012. The increase in

revenue for the nine months ended was mainly the result of increases in sales in our Orthobiologics and Ophthalmic product lines.

The following table presents product revenue by group for the three and nine-month periods ended September 30, 2012 and 2011:

	Three Months Ended		Increase (Decrease)		
	September 30,		\$	%	%
	2012	2011			
Orthobiologics	\$9,242,783	\$10,377,222	\$(1,134,439 )	-11	%
Dermal	376,251	947,122	(570,871 )	-60	%
Ophthalmic	1,891,433	4,562,574	(2,671,141 )	-59	%
Surgical	1,426,273	1,068,522	357,751	33	%
Veterinary	1,118,700	800,560	318,140	40	%
	\$14,055,440	\$17,756,000	\$(3,700,560 )	-21	%

  

	Nine Months Ended September		Increase (Decrease)		
	30,		\$	%	%
	2012	2011			
Orthobiologics	\$30,262,991	\$28,177,115	\$2,085,876	7	%
Dermal	1,033,302	2,335,881	(1,302,579 )	-56	%
Ophthalmic	8,515,160	8,045,203	469,957	6	%
Surgical	3,874,405	3,748,277	126,128	3	%
Veterinary	2,865,187	1,924,364	940,823	49	%
	\$46,551,045	\$44,230,840	\$2,320,205	5	%

#### Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. As noted in the table above, sales decreased 11% for the three months ended September 30, 2012, but increased 7% for the nine months then ended compared to the same periods in 2011. The year-over-year decrease for the three-month period ended September 30, 2012 was primarily due to temporary scale-up issue experienced as we consolidated all of our manufacturing activities into our Bedford Facility from our now-closed Woburn, Massachusetts facility. These temporary production issues resulted in the loss of a batch of in-process ORTHOVISC product. The Company estimates that the temporary production issues resulted in the deferral of approximately \$2.8 million in sales in the quarter, which the Company expects to ship during the fourth quarter of 2012. The year-over-year increase for the nine-month period ended September 30, 2012 was primarily due to DePuy Mitek's continued market penetration efforts in the U.S. for ORTHOVISC.

#### Dermal

Our dermal franchise consists of advanced wound care products and aesthetic dermal fillers. Overall, dermal product sales decreased 60% and 56% for the three and nine-month periods ended September 30, 2012, respectively, to \$376,251 and \$1,033,302, primarily due to lower sales in Italy and the U.S. for our advanced wound care products. Aesthetic product sales to our Korean distributor increased 20% year-to-date due to order timing. Anika's advanced wound care products treat skin wounds ranging from burns to diabetic ulcers. Leading products include Hyalograft 3D, Hyalofill, and Hyalomatrix. The dermal products' market is crowded with many products, and our sales expectations in this area continue to be modest for 2012.

#### Ophthalmic



Our ophthalmic franchise consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales decreased 59% to \$1,891,433 for the three-month period ended September 30, 2012, as compared to the same period in 2011. The decrease was attributed to the previously-discussed changes in the B&L contract resulting in lower anticipated volumes. Ophthalmic product sales still increased 6% to \$8,515,160 for the nine-month period ended September 30, 2012, as compared to the same period in 2011. This was primarily attributable to increased sales to B&L experienced through the first six months of 2012 as compared to the same periods ended in 2011. As previously disclosed, we expect overall ophthalmic revenue to be lower in 2012, compared to 2011, as B&L continues its transition to a formerly affiliated alternative supplier, and Anika performs a secondary supplier role.

## Surgical

Our surgical franchise consists of products used to prevent post-surgical adhesions in abdominal and spinal disorders, as well as in ear, nose and throat (“ENT”) disorders. Sales of our surgical products increased 33% and 3% to \$1,426,273 and \$3,874,405 for the three and nine-month periods ended September 30, 2012, respectively, as compared to the same periods in 2011. Our anti-adhesion products include Hyalobarrier and INCERT. Hyalobarrier had increased sales in both Europe and Asia compared to the same periods last year. Sales of our ENT product sold through our worldwide partner, Medtronic, grew significantly in the third quarter, but are still slightly lower for the nine-month period ended September 30, 2012, as compared to the same periods in the prior year, primarily due to order timing.

## Veterinary

Veterinary revenue from HYVISC increased 40% and 49% to \$1,118,700 and \$2,865,187 for the three and nine-month periods ended September 30, 2012, respectively. The increases were primarily due to increased demand by our distribution partner, Boehringer Ingelheim Vetmedica, and their expanded distribution into the Middle East. We expect overall HYVISC revenue to be higher for 2012, as compared to the same period ended 2011.

## Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three and nine-month periods ended September 30, 2012 was \$711,171 and \$2,200,995, respectively, as compared to \$699,817 and \$2,103,508, respectively, for the same periods in 2011. Licensing and milestone revenue includes the ratable recognition of the \$27,000,000 in up-front and milestone payments related to the U.S. distribution agreement with Depuy Mitek received in 2004. These amounts are being recognized in income over the ten-year expected life of the agreement, or \$2,700,000 per year. In December 2011, the Company also entered into a fifteen-year licensing and supply agreement with DePuy Mitek to market MONOVISC in the U.S. The Company received an initial payment of \$2,500,000 in December 2011, which will be recognized ratably over the fifteen year term of that agreement.

## Product gross profit and margin

Product gross profit for the three and nine-month periods ended September 30, 2012 was \$6,834,412 and \$24,832,310, or 49% and 53% of product revenue for each period, respectively. Product gross profit for the three and nine-month periods ended September 30, 2011 was \$10,361,078 and \$24,575,552, or 58% and 56% of product revenue for each period, respectively. The decrease in gross profit for the three-month period ended September 30, 2012, as compared to the same period in 2011, is directly attributable to the temporary scale-up issue experienced as we consolidated all of our manufacturing activities into our Bedford Facility from our now-closed Woburn, Massachusetts facility. This production issue, which has been resolved, resulted in the loss of time and in-process inventory of ORTHOVISC, and resulted in the deferral of revenue as previously discussed under “Orthobiologics”. Gross profit as a percentage of product sales for the nine-month period ended September 30, 2012 decreased, as compared to the same period in 2011, as the modest gains in gross margin experienced in the first half of the year from a more favorable product mix were more than offset by the effects of the scale-up issue discussed above.

The Company plans to transfer a significant portion of the Anika S.r.l. product manufacturing to its location in Bedford, MA over the next two years, starting with the ACP gel products. As this transfer takes place it is expected to have a favorable impact on gross margin starting in the first half of 2013. Looking forward, we expect gross margin in the U.S. to remain under pressure from government healthcare cost control initiatives. We have received all FDA approvals required to manufacture our aseptic products in our Bedford Facility. Commencing with these FDA Bedford facility approvals, annual depreciation expense increased approximately \$1.5 million starting in March 2012. In June 2012, we completed the closure of our former Woburn manufacturing facility and our lease agreement for that facility

is now expired. Annual operating expenses for the Woburn facility were approximately \$2.5 million.

#### Research and development

Research and development expenses for the three and nine-month periods ended September 30, 2012 were \$1,217,086 and \$4,048,359, respectively, or 8% of total revenue for each period, and reflect decreased levels of clinical study spending as compared to the same periods in 2011. Spending is expected to increase in future quarters with increased expenditures planned on clinical trials as well as on the further development of Anika's pipeline of new products based on our technology assets.

### Selling, general and administrative

Selling, general and administrative (“SG&A”) expenses for the three and nine-month periods ended September 30, 2012 were \$3,601,737 and \$11,061,256, respectively, or 24% and 23% of total revenue. SG&A expenses for the three and nine-month periods ended September 30, 2011 were \$4,712,178 and \$12,989,268, respectively, or 26% and 28% of total revenue. These decreases, as compared to the same periods in 2011, were primarily due to placing in service the remainder of the Bedford manufacturing facility, and lower legal and professional fees, partially offset by exit costs associated with the closing of our Woburn facility. Prior to March 2012, the previously unoccupied space was expensed to SG&A. As previously disclosed, we expect general and administrative expenses to be lower in 2012 compared to 2011, and to grow modestly in future years.

### Interest income (expense), net

Net interest expense was \$45,161 and \$145,493 for the three and nine-month periods ended September 30, 2012, respectively, as compared to \$46,269 and \$132,471 for the same periods in the prior year. The increase in interest expense for the nine month period is due to a higher interest rate in 2012 as compared to 2011, partially offset by lower average outstanding debt.

### Income taxes

Provisions for income taxes were \$1,036,349 and \$4,483,960 for the three and nine-month periods ended September 30, 2012, respectively, based on effective tax rates of 38.6 % and 38.1 %. Provisions for income taxes were \$1,794,575 and \$3,335,576 for the three and nine-month periods ended September 30, 2011, respectively, based on effective tax rates of 37.6% and 37.4%. The increase in the effective tax rates for the periods ended 2012, as compared to the same periods in the previous year, are primarily due to lower tax credits anticipated in the current year, including the federal R&D credit which expired with the 2011 tax year, combined with larger losses experienced by Anika S.r.l. as compared to the same periods in 2011.

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 2009 through 2011 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The 2009 through 2011 tax years remain subject to examination by the appropriate governmental authorities for 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 and its investment tax credit carryforward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that 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, 2012 or December 31, 2011, respectively.

### 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 and debt, meeting our cash requirements. Cash and cash equivalents totaled approximately \$39.9 million and \$35.8 million at September 30, 2012 and December 31, 2011, respectively. Working capital totaled approximately \$56.2 million at September 30, 2012 and \$49.6 million at December 31, 2011, respectively. The Company believes it has adequate financial resources to

support its business for the next twelve months.

Cash provided by operating activities was \$5,736,296 for the nine months ended September 30, 2012 as compared to cash provided by operating activities of \$2,865,813 for the same period in the prior year. This increase in cash provided by operations was due primarily to increased profitability in 2012, partially offset by an increase in net working capital requirements, as compared to the same period in 2011, related to the Company's growth.

Cash used in investing activities was \$1,292,487 for the nine months ended September 30, 2012 as compared to \$953,952 for the same period in 2011. The increase is primarily due to planned capital projects associated with maintaining our Bedford facility. We expect overall capital spending during 2012 to be higher than in 2011 due to the completion of the capital maintenance projects combined with the planned transfer of manufacturing activities for certain Anika S.r.l. products from Italy to our Bedford facility.

Cash used in financing activities was \$411,565 for the nine months ended September 30, 2012, as compared to \$1,048,230 for the same period in 2011. The decrease in cash used is attributable to the income tax benefits associated with employee stock option exercises received during the first nine months of 2012, as well as additional proceeds from exercise of stock options as compared to the same period in the prior year.

#### Critical Accounting Estimates

There have been no significant changes in our critical accounting estimates during the nine months ended September 30, 2012, 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, 2011.

#### Recent Accounting Pronouncements

Information with respect to Recent Accounting Pronouncements may be found in Note 3 of the Notes to Condensed Consolidated Financial Statements (unaudited) in this Form 10-Q, which information is incorporated herein by reference.

#### Contractual Obligations and Other Commercial Commitments

We have made significant capital investments related to the build-out and validation of our facility in Bedford, Massachusetts. This capital project has been financed with cash on hand and the proceeds of a \$16,000,000 unsecured Credit Agreement with Bank of America entered into on January 31, 2008. This term loan has quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. We commenced making quarterly principal payments on March 31, 2009. Total debt outstanding was \$10,000,000 as of September 30, 2012. Interest is payable at a rate based upon (at the Company's election) either Bank of America's prime rate or LIBOR plus 125 basis points.

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 has not entered into any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on the Company's financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

## ITEM QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

3.

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, 2011.

As of September 30, 2012, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments for which fair value disclosure would be required under ASC 825, Financial Instruments, and ASC 815, Derivatives and Hedging. Our investments consist of money market funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

### Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk and 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 nine months ended September 30, 2012. 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 \$286,031 during the first nine months of 2012.

Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations, changes in credit quality of the issuer or otherwise. As of September 30, 2012, we were subject to interest rate risk on \$10 million of variable rate debt. The interest payable on our debt is determined, at the Company's option, based on LIBOR plus 1.25% or the lender's prime rate and, therefore, is affected by changes in market interest rates. Based on the outstanding debt amount as of September 30, 2012, we would have a decrease in future annual cash flow of approximately \$92,000 for every 1% increase in the interest rate over the next twelve month period.

## ITEM CONTROLS AND PROCEDURES

4.

### (a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in 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 quarter ended September 30, 2012 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.



## PART II: OTHER INFORMATION

### ITEM LEGAL PROCEEDINGS

1.

On July 7, 2010, Genzyme Corporation (“Genzyme”) 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 alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. On April 26, 2011, Genzyme filed a motion to add its newly-issued U.S. Patent No. 7,931,030 to this litigation and also filed a separate new complaint in the District of Massachusetts alleging that the Company's manufacture and sale of MONOVISC in the United States will infringe that patent. On May 23, 2011, the Court entered orders permitting Genzyme to file its supplemental complaint adding its newly-issued U.S. Patent No. 7,931,030 to this litigation and requiring Genzyme to withdraw its separately filed complaint. On July 14, 2011, the Company filed an answer to the supplemental complaint, denying liability. On May 10, 2012, Genzyme dismissed its claims of infringement of U.S. Patent No. 5,399,351 and is no longer asserting that patent against the Company. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with Depuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product. On September 19, 2012, Genzyme and the Company jointly requested that the Court stay Genzyme's lawsuit against the Company pending the full resolution of the Seikagaku/Zimmer lawsuit, including through any appeal of the judgment entered in that lawsuit. The District Court granted the motion on September 28, 2012.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging, discovered by the Company. We have settled the matter related to this dispute with Medtronic. As this error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A., we have made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the Anika S.r.l. acquisition. Management has assessed Fidia's claim and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for any related loss contingency.

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 RISK FACTORS

1A.

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, 2011, except to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q relates to such risk factors. 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, 2011, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

ITEM 6. EXHIBITS

Exhibit No.	Description
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Kevin W. Quinlan 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 Kevin W. Quinlan, 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, 2012, as filed with the SEC on November 8, 2012, formatted in XBRL (eXtensible Business Reporting Language), as follows: <ul style="list-style-type: none"> <li>i. Condensed Consolidated Balance Sheets as of September 30, 2012 (unaudited) and December 31, 2011</li> <li>ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2012 and September 30, 2011 (unaudited)</li> <li>iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and September 30, 2011 (unaudited)</li> <li>iv. Notes to Condensed Consolidated Financial Statements (unaudited)</li> </ul>

\* Filed herewith

\*\* Furnished herewith.

§ As provided in Rule 406T of Regulation S-T, this information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933, as amended, and Section 18 of the Securities Exchange Act of 1934, as amended.

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.

November 8, 2012

By:

/s/ KEVIN W. QUINLAN  
Kevin W. Quinlan

Chief Financial Officer  
(Authorized Officer and Principal Financial  
Officer)