

ANIKA THERAPEUTICS INC  
Form 10-Q  
November 05, 2013

---

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

---

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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

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

---

Commission File Number 000-21326

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

Massachusetts  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

01730  
(Zip Code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Yes  No

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

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, 2013 there were 13,825,542 outstanding shares of Common Stock, par value \$.01 per share.

---

PART I:  
ITEM 1.FINANCIAL INFORMATION  
FINANCIAL STATEMENTSAnika Therapeutics, Inc. and Subsidiaries  
Condensed Consolidated Balance Sheets  
(unaudited)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 64,055,438	\$ 44,067,477
Accounts receivable, net of reserves of \$369,989 and \$337,459 at September 30, 2013 and December 31, 2012, respectively	16,496,917	21,462,481
Inventories	11,582,492	8,283,472
Current portion deferred income taxes	1,989,422	2,031,583
Prepaid expenses and other	878,472	1,539,477
Total current assets	95,002,741	77,384,490
Property and equipment, at cost	52,067,759	52,376,013
Less: accumulated depreciation	(18,805,895 )	(17,263,032 )
	33,261,864	35,112,981
Long-term deposits and other	145,563	171,053
Intangible assets, net	19,197,226	20,334,636
Goodwill	9,275,130	9,065,891
Total Assets	\$ 156,882,524	\$ 142,069,051
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,136,679	\$ 2,341,838
Accrued expenses	5,228,399	5,837,044
Deferred revenue	850,067	2,875,067
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	542,302	1,798,669
Total current liabilities	10,357,447	14,452,618
Other long-term liabilities	1,172,099	1,541,124
Long-term deferred revenue	2,027,778	2,152,778
Deferred tax liability	8,319,038	6,997,397
Long-term debt	6,800,000	8,000,000
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, 2013 and December 31, 2012, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 14,266,098 and 13,866,060 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	142,661	138,659
Additional paid-in-capital	70,281,179	65,431,424
Accumulated currency translation adjustment	(2,147,511 )	(2,654,630 )
Retained earnings	59,929,833	46,009,681
Total stockholders' equity	128,206,162	108,925,134

Total Liabilities and Stockholders' Equity	\$ 156,882,524	\$ 142,069,051
--	----------------	----------------

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,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 13,920,152	\$ 7,294,237
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,579,474	3,364,432
Stock-based compensation expense	1,156,929	914,003
Deferred income taxes	2,022,965	(1,012,571 )
Provision for doubtful accounts	24,098	135,353
Provision for inventory	165,803	790,379
Gain on sale of assets	(442,341 )	-
Tax benefit from exercise of stock options	(764,181 )	(456,796 )
Changes in operating assets and liabilities:		
Accounts receivable	4,667,839	716,874
Inventories	(3,430,655 )	(2,433,367 )
Prepaid expenses, other current and long-term assets	531,449	429,718
Long-term deposits and other	25,497	25,496
Accounts payable	124,679	(2,399,999 )
Accrued expenses	(642,430 )	(873,153 )
Deferred revenue	(2,150,000 )	(2,150,000 )
Income taxes payable	(1,256,367 )	1,398,008
Other long-term liabilities	(373,712 )	(6,318 )
Net cash provided by operating activities	17,159,199	5,736,296
Cash flows from investing activities:		
Proceeds from sale of assets	530,865	-
Purchase of property and equipment	(235,803 )	(1,292,487 )
Net cash provided by (used in) investing activities	295,062	(1,292,487 )
Cash flows from financing activities:		
Principal payments on debt	(1,200,000 )	(1,200,000 )
Proceeds from exercise of stock options	2,932,649	331,639
Tax benefit from exercise of stock options	764,181	456,796
Net cash provided by (used in) financing activities	2,496,830	(411,565 )
Exchange rate impact on cash	36,870	46,390
Increase in cash and cash equivalents	19,987,961	4,078,634
Cash and cash equivalents at beginning of period	44,067,477	35,777,222
Cash and cash equivalents at end of period	\$ 64,055,438	\$ 39,855,856

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, manufactures and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (“HA”), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with 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, 2013 and the results of its operations for the three and nine months ended September 30, 2013 and 2012 and cash flows for the nine months ended September 30, 2013 and 2012.

Pursuant to the Health Care and Education Reconciliation Act of 2010 and in conjunction with the Patient Protection and Affordable Care Act, a medical device excise tax (“MDET”) became effective on January 1, 2013 for sales of certain medical devices. Some of our product sales are subject to the provisions of the MDET. The Company has elected to recognize any amounts related to the MDET under the gross method as allowed under Accounting Standards Codification (“ASC”) 605-45. For the three and nine-month periods ended September 30, 2013, amounts included in revenue and cost of goods sold for MDET were immaterial. There have been no other changes in our significant accounting policies for the three and nine months ended September 30, 2013 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

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, 2012. The results of operations for the three and nine months ended September 30, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013. 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



In February 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. The provisions of ASU 2013-02 are effective for annual and interim periods beginning after December 15, 2012. The objective of this update is to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments in this update seek to attain that objective by requiring an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. generally accepted accounting principles to be reclassified in its entirety to net income. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In March 2013, the FASB issued ASU No. 2013-05, Foreign Currency Matters (Topic 830): Parent’s Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity. The provisions of ASU 2013-05 are effective for annual and interim periods beginning after December 15, 2013. The objective of the amendments in this update is to resolve the diversity in practice about whether Subtopic 810-10, Consolidation—Overall, or Subtopic 830-30, Foreign Currency Matters—Translation of Financial Statements, applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. The adoption of this amendment will not have a material impact on our consolidated financial position, results of operations, or cash flows.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. The provisions of ASU 2013-11 are effective for annual and interim periods beginning after December 15, 2013. The main provisions of ASU 2013-11 require an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented in the financial statements as a reduction to a deferred tax asset for the following; a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, with certain exceptions. 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.

Cash equivalents in money market accounts measured and recorded at fair value on a recurring basis was \$34,264,268 at September 30, 2013 and December 31, 2012, and were classified as Level 1 instruments.

#### 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, 2013 and 2012, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,	
	2013	2012
Risk free interest rate	-	0.63%
Expected volatility	-	57.60%
Expected lives (years)	-	4
Expected dividend yield	-	0.00%

  

	Nine Months Ended September 30,			
	2013		2012	
Risk free interest rate	0.61%	- 0.70%	0.63%	- 0.64%

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Expected volatility	57.60%	57.60%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

6

---

The Company recorded \$368,603 and \$1,156,929 of share-based compensation expense for the three and nine months ended September 30, 2013, respectively, for equity compensation awards. 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 presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the respective employees.

At the 2013 Annual Meeting of Stockholders on June 18, 2013, the shareholders of the Company approved the amendment to the Anika Therapeutics, Inc. Second Amended and Restated 2003 Stock Option and Incentive Plan (the "2003 Plan"), which among other things, increased the number of shares reserved for issuance under the Company's stock option and incentive plan by 650,000 to 3,800,000 shares.

There were 374,500 stock options granted under the Plan during the nine months ended September 30, 2013. 13,800 restricted stock units ("RSUs") were granted to members of the Company's Board of Directors under the Plan during the three months ended March 31, 2013. The stock options and RSUs granted to employees and directors become exercisable or vest ratably over four years from the date of grant. No stock options or RSUs were granted to employees or members of the Company's Board of Directors during the three months ended September 30, 2013.

As of September 30, 2013, there was approximately \$2.7 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 2.7 years.

The total intrinsic value of stock options and SARs exercised during the nine-month periods ended September 30, 2013 and 2012 was \$4,095,833 and \$1,643,502 respectively. Cash received from the exercise of stock options during the three and nine-month periods ended September 30, 2013 was \$1,804,773 and \$2,932,649, 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.

There were approximately 1.7 million options and SARs outstanding under the Company's incentive plans at September 30, 2013 with a weighted-average exercise price of \$8.71 per share, an aggregate intrinsic value of approximately \$25.2 million, and a weighted-average remaining contractual term of 6.5 years.

None of the options or SARs outstanding at September 30, 2013 or 2012, 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, 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 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, 2013 and 2012 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Shares used in the calculation of basic earnings per share	13,682,449	13,287,463	13,534,334	13,237,629
Effect of dilutive securities:				
Stock options, SARs, and RSAs, and shares held in escrow	1,276,516	1,171,691	1,139,545	1,120,162
Diluted shares used in the calculation of earnings per share	14,958,965	14,459,154	14,673,879	14,357,791

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

#### 7. Inventories

Inventories consist of the following:

	September 30, 2013	December 31, 2012
Raw materials	\$ 5,991,492	\$ 6,109,807
Work-in-process	2,453,647	777,056
Finished goods	3,137,353	1,396,609
Total	\$ 11,582,492	\$ 8,283,472

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, 2013 and December 31, 2012 consist of the following:

	September 30, 2013			December 31, 2012		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$ 16,700,000	\$(1,161,777)	\$ (3,731,121)	\$ 11,807,102	\$ 12,370,042	15
In-process research & development	5,502,686	(310,550 )	-	5,192,136	4,980,574	Indefinite
Distributor relationships	4,700,000	(440,316 )	(3,189,671)	1,070,013	1,733,453	5
Patents	1,000,000	(67,334 )	(212,079 )	720,587	749,166	16
Eleless trade name	1,000,000	-	(592,612 )	407,388	501,401	9
Total	\$ 28,902,686	\$(1,979,977)	\$ (7,725,483)	\$ 19,197,226	\$ 20,334,636	

The aggregate amortization expense related to intangible assets was \$521,387 and \$494,301 for the three months ended September 30, 2013 and 2012, respectively. The aggregate amortization expense for the nine months ended September 30, 2013 and 2012 was \$1,555,796 and \$1,517,285 respectively.

Changes in the carrying value of goodwill for the three and nine months ended September 30, 2013 were as follows:

		For the three months ended September 30, 2013		For the nine months ended September 30, 2013
Balance, beginning	\$	8,923,197	\$	9,065,891
Effect of foreign currency adjustments		351,933		209,239
Balance, ending	\$	9,275,130	\$	9,275,130

#### 9. Accrued Expenses

Accrued expenses consist of the following:

		September 30, 2013		December 31, 2012
Payroll and benefits	\$	2,558,293	\$	2,477,833
Professional fees		389,672		642,853
Clinical trial costs		190,362		102,414
Restructuring costs		208,207		933,732
Other		1,881,865		1,680,212
Total	\$	5,228,399	\$	5,837,044

#### 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 District 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 claim 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 District 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 September 2013, the District Court in the Seikagaku/Zimmer lawsuit issued an order denying all the post-trial motions in the case, except for Seikagaku/Zimmer's motion for damages against Genzyme. On October 14, 2013, Genzyme filed a notice of appeal to the United States Court of Appeals for the Federal circuit challenging the District Court's judgment of invalidity and non-infringement. The appeal is currently pending. As to Seikagaku/Zimmer's motion for damages, the District Court held a scheduling conference on October 30, 2013 and issued a scheduling order on October 31, 2013.

In 2011, Merogel Injectable was voluntarily withdrawn from the market due to a labeling error on the product's packaging. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error related to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. ("Fidia") and, as a result, we made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia maintained that it did not have liability for this matter, and asserted a counterclaim against Anika for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. The Company reached agreement with Fidia in October 2013 to settle this matter without admission of liability by either party in return for a payment made by Fidia to the Company. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and shares previously held in escrow have been released.

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, 2013, the Company had an outstanding debt balance of \$8,400,000, at an interest rate of 1.43%. 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 \$8,400,000 and \$9,600,000 at September 30, 2013 and December 31, 2012, 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, 2013 and December 31, 2012, respectively.

#### 12. Income Taxes

Provisions for income taxes were \$2,776,199 and \$8,147,282 for the three and nine-month periods ended September 30, 2013, based on effective tax rates of 35.9 % and 36.9%, respectively. 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%. The decrease in the effective tax rate for the periods ended 2013, as compared to the same periods in the previous year, is primarily due to increases in anticipated tax credits and the tax benefits associated with increased incentive stock option exercise activity in the periods ended 2013 as compared to 2012.

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 2010 through 2012 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The 2009 through 2012 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, 2013 or December 31, 2012, respectively.

13.

Related Party

In connection with our acquisition of Anika S.r.l. on December 30, 2009, Fidia acquired ownership of 1,981,192 shares of the Company's common stock, of which 500,000 shares remained in escrow at September 30, 2013. On August 6, 2013, Fidia sold 1,270,000 shares of Anika Therapeutics, Inc. common stock and as of September 30, 2013, Fidia owns 711,192 shares of the Company, or just less than 5% of the outstanding shares of the Company and, under the guidance provided by ASC 850, Related Party Disclosures, Fidia is no longer considered a related party to the Company.

10

---

## 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,	
	2013	2012	2013	2012
Orthobiologics	\$ 12,830,566	\$ 9,242,783	\$ 40,620,339	\$ 30,262,991
Dermal	267,766	376,251	1,066,409	1,033,302
Surgical	1,136,248	1,426,273	3,955,134	3,874,405
Ophthalmic	1,425,609	1,891,433	2,818,407	8,515,160
Veterinary	1,363,157	1,118,700	3,124,953	2,865,187
Product revenue	\$ 17,023,346	\$ 14,055,440	\$ 51,585,242	\$ 46,551,045

Total revenue by geographic location in total and as a percentage of total revenue, for the three and nine months ended September 30, 2013 and 2012 are as follows (prior period numbers have been reclassified to conform to current period presentation):

Geographic Location:	Three Months Ended September 30, 2013		Three Months Ended September 30, 2012	
	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue
United States	\$14,485,821	82 %	\$12,628,612	86 %
Europe	1,656,656	9 %	1,064,165	7 %
Other	1,611,961	9 %	1,073,834	7 %
Total revenue	\$17,754,438	100 %	\$14,766,611	100 %

Geographic Location:	Nine Months Ended September 30, 2013		Nine Months Ended September 30, 2012	
	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue
United States	\$42,251,336	78 %	\$40,463,657	83 %
Europe	5,226,619	10 %	3,993,708	8 %
Other	6,351,871	12 %	4,294,675	9 %
Total revenue	\$53,829,826	100 %	\$48,752,040	100 %

## 15. Restructuring Charges

In December 2012, the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards, effective January 1, 2013, established by the European Medicines Agency (“EMA”) for Advanced Therapy Medicinal Products. 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 related to the non-cash termination and related impairment of an IPR&D project, \$0.3 million related to the disposal of property and equipment, and \$0.1 million related to the disposal of inventory. Accrued restructuring charges of \$0.9 million, as of December 31, 2012, were primarily related to employee termination costs. A majority of the cash payments are anticipated to occur in 2013.

We were substantially completed with the restructuring plan as of June 30, 2013. Certain previously impaired and written-off equipment were sold, resulting in restructuring credit of \$196,084 and \$442,869 in the three and nine months ended September 30, 2013, respectively. The carrying value of the restructuring accrual approximated fair value at September 30, 2013.

The following table summarizes restructuring accrual activity for the nine months ended September 30, 2013:

	Restructuring Accrual		
	Employee Severance and Related Benefits	Activity Termination and Facility Closure Costs	Total
December 31, 2012	\$801,453	\$ 132,279	\$933,732
Cash Proceeds, Disbursements	(613,870)	(124,488 )	(738,358)
Foreign Exchange Impact	12,814	19	12,833
September 30, 2013	\$200,397	\$ 7,810	\$208,207

ITEM 2.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND 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 and line-extension 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 our ability 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 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 license our aesthetics product to new distribution partners domestically and 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 expectations regarding development of aesthetics product line extensions;

- Our expectations regarding product gross margin;
- Our expectations regarding our U.S. MONOVISC premarket approval (“PMA”) filing with the FDA, including the escalation of the appeal process with the FDA and the outcome of FDA’s review of the additional information requested from us, and the likelihood of our obtaining such approval and/or the anticipated timing thereof;
- Our expectations regarding CINGAL™, including the expense associated therewith, and our ability to obtain regulatory approvals for this product;
- 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 ability to 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 ability 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; 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, 2012. 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, 2012 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 therapeutic use. 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, primarily in Europe. These products are also all made from hyaluronic acid, 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		
Advanced wound care		X
Aesthetic dermatology	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care (“ENT”)		X
Ophthalmic	X	
Veterinary	X	

In December 2012, the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards established by the EMA for Advanced Therapy Medicinal Products (“ATMP”) (cell based) products that were effective January 1, 2013. The Company adopted a restructuring plan which included a reduction-in-force of 12 people and provided for severance payments and the disposal of related supplies, equipment, and other assets. The plan was intended to improve the efficiency and financial performance of the Company’s Italian operations by reducing costs and focusing on products and technology with strong commercial potential. We were substantially completed with the implementation of the restructuring plan as of June 30, 2013.

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, 2012, 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 tissue protection, healing and repair. Our investment in R&D varies considerably depending on the 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.

Two key products currently under development or regulatory review include MONOVISC for U.S. marketing approval and CINGAL. 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. In December 2012, the FDA upheld its non-approvable decision following our appeal. Subsequent to that decision, in February and July 2013, the Company submitted PMA amendments. The latest amendment is under review by the FDA. The Company continues to discuss pathways for MONOVISC approval with the Agency.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule designed to provide broad pain relief for a longer period of time. We have completed the formulation and biocompatibility studies of the product. During the second quarter of 2013, we commenced the clinical trial to obtain the needed clinical data for a CE Mark submission and approval, and to support other product registrations including in the United States.

The technologies obtained through our acquisition of Anika S.r.l. have enhanced our research and development capabilities, and our pipeline of candidate products. Anika S.r.l. has research and development programs for products including Hyalofast, an innovative, biodegradable support for human bone marrow mesenchymal stem cells used in connection with soft tissue regeneration, and Hyalospine, an adhesion prevention gel for use after spinal surgery.

#### 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 District 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 claim 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 District 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 September 2013, the District Court in the Seikagaku/Zimmer lawsuit issued an order denying all the post-trial motions in the case, except for Seikagaku/Zimmer's motion for damages against Genzyme. On October 14, 2013, Genzyme filed a notice of appeal to the United States Court of Appeals for the Federal circuit challenging the District Court's judgment of invalidity and non-infringement. The appeal is currently pending. As to Seikagaku/Zimmer's motion for damages, the District Court held a scheduling conference on October 30, 2013 and issued a scheduling order on October 31, 2013.

In 2011, Merogel Injectable was voluntarily withdrawn from the market due to a labeling error on the product's packaging. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error related to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. (“Fidia”) and, as a result, we made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia maintained that it did not have liability for this matter, and asserted a counterclaim against Anika for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. The Company reached agreement with Fidia in October 2013 to settle this matter without admission of liability by either party in return for a payment

made by Fidia to the Company. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and shares previously held in escrow have been released.

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, 2013 Compared to the Three and Nine Months Ended September 30, 2012

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Inc/(Dec)	2013	2012	Inc/(Dec)
Product revenue	\$17,023,346	\$14,055,440	21 %	\$51,585,242	\$46,551,045	11 %
Licensing, milestone and contract revenue	731,092	711,171	3 %	2,244,584	2,200,995	2 %
Total revenue	17,754,438	14,766,611	20 %	53,829,826	48,752,040	10 %
Operating expenses:						
Cost of product revenue	5,377,568	7,221,028	(26 %)	16,530,070	21,718,735	(24 %)
Research & development	1,618,012	1,217,086	33 %	5,029,974	4,048,359	24 %
Selling, general & administrative	3,188,669	3,601,737	(11 %)	10,536,462	11,061,256	(5 %)
Restructuring charges	(196,084 )	-	N/M	(442,869 )	-	N/M
Total operating expenses	9,988,165	12,039,851	(17 %)	31,653,637	36,828,350	(14 %)
Income from operations	7,766,273	2,726,760	185 %	22,176,189	11,923,690	86 %
Interest income (expense), net	(32,816 )	(45,161 )	(27 %)	(108,755 )	(145,493 )	(25 %)
Income before income taxes	7,733,457	2,681,599	188 %	22,067,434	11,778,197	87 %
Provision for income taxes	2,776,199	1,036,349	168 %	8,147,282	4,483,960	82 %
Net income	\$4,957,258	\$1,645,250	201 %	\$13,920,152	\$7,294,237	91 %
Product gross profit	\$11,645,778	\$6,834,412	70 %	\$35,055,172	\$24,832,310	41 %
Product gross margin	68 %	49 %		68 %	53 %	

## Product Revenue

Product revenue for the quarter ended September 30, 2013 was \$17,023,346, an increase of 21%, as compared to \$14,055,440 for the quarter ended September 30, 2012. Product revenue for the nine months ended September 30, 2013 was \$51,585,242, an increase of 11%, as compared to \$46,551,045 for the nine months ended September 30, 2012. The increases in each of the three and nine-month periods were primarily driven by an increase in sales of our Orthobiologics products, as compared to the same periods in the prior year, when we experienced the previously-disclosed temporary scale-up issue at our Bedford, MA manufacturing facility. For the three and nine months ended September 30, 2013, increases in sales of Orthobiologics products were partially offset by the expected decline in sales of our Ophthalmic product line, as compared to the same periods in the prior year.

The following table presents product revenue by group for the three and nine-month periods ended September 30, 2013 and 2012:

	Three Months Ended September 30,		Increase (Decrease)	
	2013	2012	\$	%
Orthobiologics	\$ 12,830,566	\$ 9,242,783	\$3,587,783	39 %
Dermal	267,766	376,251	(108,485 )	(29 %)
Surgical	1,136,248	1,426,273	(290,025 )	(20 %)
Ophthalmic	1,425,609	1,891,433	(465,824 )	(25 %)

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Veterinary	1,363,157	1,118,700	244,457	22	%
	\$ 17,023,346	\$ 14,055,440	\$2,967,906	21	%

Nine Months Ended September

	30,		Increase (Decrease)		
	2013	2012	\$	%	
Orthobiologics	\$ 40,620,339	\$ 30,262,991	\$10,357,348	34	%
Dermal	1,066,409	1,033,302	33,107	3	%
Surgical	3,955,134	3,874,405	80,729	2	%
Ophthalmic	2,818,407	8,515,160	(5,696,753 )	(67	%)
Veterinary	3,124,953	2,865,187	259,766	9	%
	\$ 51,585,242	\$ 46,551,045	\$5,034,197	11	%

### Orthobiologics

Our Orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 39% and 34% for the three and nine months ended September 30, 2013, respectively, compared to the same periods in 2012, primarily due to DePuy Mitek's continued market penetration efforts in the U.S. for ORTHOVISC, combined with strong year-over-year increases in international sales of our viscosupplementation products ORTHOVISC and MONOVISC. The improvement in international product revenue was primarily due to increased sales in Europe and Canada. The growth rates in the three and nine-month periods ended September 30, 2013 are not indicative of fourth quarter and full year results for 2013 due to several factors, including the deferral of revenue from the third quarter to the fourth quarter of 2012 as a result of the temporary scale-up issue at our Bedford, MA manufacturing facility, as well as any potential inventory management order activity by DePuy Mitek. Overall, we expect Orthobiologics product revenue to increase in 2013 as compared to 2012, both domestically and internationally.

### Dermal

Our dermal franchise consists of advanced wound care products and aesthetic dermal fillers. Overall, dermal product sales decreased 29% for the three-month period ended September 30, 2013 to \$267,766, as compared to the same period in 2012. Sales of this product franchise increased 3% for the nine-month period ended September 30, 2013 to \$1,066,409, as compared to the same period ended in 2012, driven by increases in advanced wound care product revenue in Europe and Latin America, offset by lower sales of our aesthetic product due to order timing by our international distributors. Anika's advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers, with Hyalomatrix and Hyalofill as lead products. During the first quarter of 2013, we terminated our U.S. distribution agreement with Misonix for Hyalomatrix and we are actively working on a new domestic commercialization strategy. For the full year 2013, we expect revenue from our dermal products to increase from 2012.

### Surgical

Our surgical franchise consists of products used to prevent post-surgical adhesions in abdominal-pelvic, spinal, and ear, nose and throat ("ENT") disorders. Sales of our surgical products decreased 20% for the three-month period ended September 30, 2013 to \$1,136,248, as compared to the same period ended in 2012, due primarily to order timing of our Hyalobarrier product by our European and Asian partners. Sales of this product franchise increased 2% for the nine-month period ended September 30, 2013 to \$3,955,134 primarily due to sales of our ENT products to our worldwide partner, Medtronic, resulting from the re-launch of a compliant version of Merogel Injectable in the U.S. in February 2013.

### Ophthalmic

Our ophthalmic franchise consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales decreased 25% and 67% to \$1,425,609 and \$2,818,407 for the three and nine month-periods ended September 30, 2013, respectively, as compared to the same periods in 2012. The decreases were primarily attributable to the anticipated sales decline with B&L to contractually dictated minimum purchase levels. During the nine-month period ended September 30, 2012, we had approximately \$7.7 million of ophthalmic revenue from B&L as a result of their significantly higher than expected demand. As previously disclosed, the overall ophthalmic revenue will be lower in 2013, as compared to 2012, under the terms of the current Bausch & Lomb supply agreement.

### Veterinary



Veterinary revenue from HYVISC increased 22% and 9% to \$1,363,157 and \$3,124,953 for the three and nine-month periods ended September 30, 2013, respectively, as compared to the same period in 2012. The variations were primarily due to order timing by our distribution partner, Boehringer Ingelheim Vetmedica. We expect overall HYVISC revenue for 2013 to be at a higher level compared to that of 2012.

#### Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three and nine-month periods ended September 30, 2013 was \$731,092 and \$2,244,584, respectively, as compared to \$711,171 and \$2,200,995, respectively, for the same periods in 2012. 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 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 is being 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, 2013 was \$11,645,778 and \$35,055,172, or 68% of product revenue for each period, respectively. 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. The increase in product gross margin for the three and nine-month periods ended September 30, 2013, respectively, as compared to the same periods in 2012, is directly attributable to the elimination of duplicate manufacturing facility costs, manufacturing process improvements and scale efficiencies at our Bedford, Massachusetts facility, favorable product mix, as well as elimination of unprofitable tissue engineering operations since the beginning of 2013. Although we expect to continue to benefit from these positive factors, this quarter's product gross margin may not be indicative of the rest of the year due to dynamics such as future mix of our product sales.

### Research and development

Research and development expenses for the three and nine-month periods ended September 30, 2013 were \$1,618,012 and \$5,029,974, respectively, or 9% of total revenue for both periods, and reflect increased levels of clinical study spending as a result of the commencement of the phase III CINGAL clinical trial. Spending is expected to increase in future quarters with increases in patient enrollment for the CINGAL study, as well as spending on our 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, 2013 were \$3,188,669 and \$10,536,462 respectively, representing 18% and 20% of total revenue. SG&A expenses decreased for both the three and nine-month periods ended September 30, 2013 as compared to the same periods in 2012, primarily driven by the Company's ongoing cost reduction initiatives, and non-recurring legal and settlement payment to Medtronic in the third quarter of 2012 related to Merogel Injectable product, which was temporarily withdrawn from the market due to a labeling error we discovered in the product's packaging.

### Interest income (expense), net

Net interest expense was \$32,816 and \$108,755 for the three and nine-month periods ended September 30, 2013, respectively. Net interest expense decreased for both the three and nine-month periods primarily due to a lower level of interest-bearing debt in 2013 as compared to the same periods in 2012.

### Income taxes

Provisions for income taxes were \$2,776,199 and \$8,147,282 for the three and nine-month periods ended September 30, 2013, based on effective tax rates of 35.9 % and 36.9%, respectively. 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%. The decrease in the effective tax rate for the periods ended 2013, as compared to the same periods in the previous year, is primarily due to increases in anticipated tax credits and the tax benefits associated with increased incentive stock option exercise activity in the periods ended 2013 as compared to 2012.

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 2010 through 2012 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The 2009 through 2012 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, 2013 or December 31, 2012, 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, meet our cash requirements. Cash and cash equivalents totaled approximately \$64.1 million and \$44.1 million at September 30, 2013 and December 31, 2012, respectively. Working capital totaled approximately \$84.6 million at September 30, 2013 and \$62.9 million at December 31, 2012, respectively. The Company believes it has adequate financial resources to support its business for the next twelve months.

Cash provided by operating activities was \$17,159,199 for the nine months ended September 30, 2013 as compared to cash provided by operating activities of \$5,736,296 for the same period in the prior year. This increase in cash provided by operations was due primarily to increased profitability in 2013, a decrease in accounts receivable, and a decrease in net working capital, as compared to the same period in 2012.

Cash provided by investing activities was \$295,062 for the nine months ended September 30, 2013 as compared to cash used in investing activities of \$1,292,487 for the same period in 2012. The increase in cash provided by investing activities is the result of proceeds received from the sale of property and equipment relating to our reorganization at Anika S.r.l. in the beginning of 2013, partially offset by modest capital expenditures.

Cash provided by financing activities was \$2,496,830 for the nine months ended September 30, 2013, as compared to cash used in financing activities of \$411,565 for the same period in 2012. The increase in cash provided by financing activities is attributable to the proceeds received from employees' exercises of stock options during the first nine months of 2013, 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, 2013, 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, 2012.

## 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 \$8,400,000 as of September 30, 2013. 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 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, 2012.

As of September 30, 2013, 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, 2013. The impact of exchange rates related to the consolidation of the balance sheet amounts for our Anika S.r.l. subsidiary resulted in a favorable currency translation adjustment of \$507,119 during the first nine months of 2013.

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, 2013, we were subject to interest rate risk on \$8.4 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, 2013, we would have a decrease in future annual cash flow of approximately \$78,000 for every 1% increase in the interest rate over the next twelve month period.

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 quarter ended September 30, 2013 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 (“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 District 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 claim 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 District 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 September 2013, the District Court in the Seikagaku/Zimmer lawsuit issued an order denying all the post-trial motions in the case, except for Seikagaku/Zimmer's motion for damages against Genzyme. On October 14, 2013, Genzyme filed a notice of appeal to the United States Court of Appeals for the Federal circuit challenging the District Court's judgment of invalidity and non-infringement. The appeal is currently pending. As to Seikagaku/Zimmer's motion for damages, the District Court held a scheduling conference on October 30, 2013 and issued a scheduling order on October 31, 2013.

In 2011, Merogel Injectable was voluntarily withdrawn from the market due to a labeling error on the product's packaging. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error related to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. (“Fidia”) and, as a result, we made claims against Fidia for indemnification for the Company's losses related to this issue. Fidia maintained that it did not have liability for this matter, and asserted a counterclaim against the Company for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. The Company reached an agreement with Fidia in October, 2013 to settle this matter without an admission of liability by either party in return for a payment made by Fidia to the Company. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and shares previously held in escrow have been released.

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



The following information updates, and should be read in conjunction with, the previously discussed risk factors. To our knowledge, except as disclosed below, 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, 2012. In addition to the other information set forth below and 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, 2012, which could materially affect our business, financial condition or future results. The risks described below and 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.

We may not fully realize the benefits of our restructuring plan.

On December 29, 2012, the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards established by the European Medicines Agency for ATMP (cell based) products that became effective January 1, 2013. The restructuring plan adopted included a reduction-in-force of 12 people, as well as the disposal of related supplies, equipment, and other assets. The restructuring plan is substantially completed. It was intended to improve the efficiency and financial performance of the Company's Italian operations by reducing costs and focusing on products and technology with strong commercial potential. We expect no adverse legal consequences moving forward as a result of this restructuring activity. Despite the completion, there can be no assurances that the restructuring plan will produce the expected future savings or benefits to the Company.

ITEM 6.

EXHIBITS

Exhibit No.	Description
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Sylvia Cheung pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32)	Section 1350 Certifications
**32.1	Certification of Charles H. Sherwood, Ph.D. and Sylvia Cheung, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	XBRL
101*	The following materials from Anika Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, as filed with the SEC on November 5, 2013, formatted in XBRL (eXtensible Business Reporting Language), as follows:
	i. Condensed Consolidated Balance Sheets as of September 30, 2013 (unaudited) and December 31, 2012
	ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2013 and September 30, 2012 (unaudited)
	iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2013 and September 30, 2012 (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.

November 5, 2013

By:

ANIKA THERAPEUTICS, INC.

/s/ SYLVIA CHEUNG  
Sylvia Cheung  
Chief Financial Officer

(Authorized Officer and Principal Financial  
Officer)