

ANIKA THERAPEUTICS INC
Form 10-Q
May 06, 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 March 31, 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

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

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

As of May 3, 2013, there were 13,996,250 outstanding shares of Common Stock, par value \$.01 per share.

PART I: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,965,566	\$ 44,067,477
Accounts receivable, net of reserves of \$327,270 and \$337,459 at March 31, 2013 and December 31, 2012, respectively	14,784,266	21,462,481
Inventories	9,947,961	8,283,472
Current portion deferred income taxes	1,989,422	2,031,583
Prepaid expenses and other	1,007,669	1,539,477
Total current assets	78,694,884	77,384,490
Property and equipment, at cost	51,566,576	52,376,013
Less: accumulated depreciation	(17,087,726)	(17,263,032)
	34,478,850	35,112,981
Long-term deposits and other	162,545	171,053
Intangible assets, net	19,229,922	20,334,636
Goodwill	8,792,165	9,065,891
Total Assets	\$ 141,358,366	\$ 142,069,051
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,696,550	\$ 2,341,838
Accrued expenses	4,252,574	5,837,044
Deferred revenue	2,191,667	2,875,067
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	-	1,798,669
Total current liabilities	10,740,791	14,452,618
Other long-term liabilities	1,294,140	1,541,124
Long-term deferred revenue	2,111,111	2,152,778
Deferred tax liability	6,784,019	6,997,397
Long-term debt	7,600,000	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 March 31, 2013 and December 31, 2012, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 14,006,135 and 13,866,060 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	140,061	138,659

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Additional paid-in-capital	67,014,641	65,431,424
Accumulated currency translation adjustment	(3,404,080)	(2,654,630)
Retained earnings	49,077,683	46,009,681
Total stockholders' equity	112,828,305	108,925,134
Total Liabilities and Stockholders' Equity	\$ 141,358,366	\$ 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 Operations and Comprehensive Income
(unaudited)

	Three Months Ended March 31,	
	2013	2012
Product revenue	\$ 14,494,489	\$ 13,613,328
Licensing, milestone and contract revenue	752,522	747,332
Total revenue	15,247,011	14,360,660
Operating expenses:		
Cost of product revenue	4,841,170	6,413,481
Research & development	1,582,910	1,533,103
Selling, general & administrative	3,947,114	3,351,016
Restructuring charges	(135,607)	-
Total operating expenses	10,235,587	11,297,600
Income from operations	5,011,424	3,063,060
Interest expense, net	(39,558)	(51,203)
Income before income taxes	4,971,866	3,011,857
Provision for income taxes	1,903,864	1,099,738
Net income	\$ 3,068,002	\$ 1,912,119
Basic net income per share:		
Net income	\$ 0.23	\$ 0.15
Basic weighted average common shares outstanding	13,406,952	13,162,824
Diluted net income per share:		
Net income	\$ 0.21	\$ 0.14
Diluted weighted average common shares outstanding	14,357,110	14,089,946
Net income	3,068,002	1,912,119
Other comprehensive income (loss)		
Foreign currency translation adjustment	(749,450)	756,461
Comprehensive income	\$ 2,318,552	\$ 2,668,580

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

Anika Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 3,068,002	\$ 1,912,119
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,202,208	986,913
Stock-based compensation expense	422,959	320,510
Deferred income taxes	(139,747)	(82,206)
Provision for inventory	258,195	49,558
Tax benefit from exercise of stock options	(64,642)	(394,076)
Changes in operating assets and liabilities:		
Accounts receivable	6,373,839	358,471
Inventories	(1,969,179)	(1,769,606)
Prepaid expenses, other current and long-term assets	705,078	(324,152)
Long-term deposits and other	8,499	8,499
Accounts payable	1,354,318	(476,940)
Accrued expenses	(2,351,133)	(1,341,407)
Deferred revenue	(725,067)	(716,667)
Income taxes payable	(1,834,739)	(215,156)
Other long-term liabilities	(239,737)	(5,509)
Net cash provided by (used in) operating activities	6,068,854	(1,689,649)
Cash flows from investing activities:		
Purchase of property and equipment, net	(35,802)	(224,059)
Proceeds from sale of property and equipment	135,607	-
Net cash provided by (used in) investing activities	99,805	(224,059)
Cash flows from financing activities:		
Principal payments on debt	(400,000)	(400,000)
Proceeds from exercise of stock options	1,097,016	114,656
Tax benefit from exercise of stock options	64,642	394,076
Net cash provided by financing activities	761,658	108,732
Exchange rate impact on cash	(32,228)	30,932
Increase (decrease) in cash and cash equivalents	6,898,089	(1,774,044)
Cash and cash equivalents at beginning of period	44,067,477	35,777,222
Cash and cash equivalents at end of period	\$ 50,965,566	\$ 34,003,178

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. (“Anika,” and together with its subsidiaries,” the “Company,” “we,” “us,” or “our”) was incorporated 1992 as a Massachusetts company. Anika 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 December 31, 2012 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 March 31, 2013 and the results of its operations for the three months ended March 31, 2013 and 2012 and cash flows for the three months ended March 31, 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 period ended March 31, 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 months ended March 31, 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 months ended March 31, 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 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.

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:

	March 31, 2013			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$ 34,264,269	\$ -	\$ -	\$ 34,264,269
	December 31, 2012			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$ 34,264,268	\$ -	\$ -	\$ 34,264,268

The carrying value of our debt instrument was \$9,200,000 and \$9,600,000 at March 31, 2013 and December 31, 2012 respectively. The estimated fair value of our debt instrument approximated book value at both dates using market observable inputs and interest rate measurements.

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 months ended March 31, 2013 and 2012 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	March 31,	
	2013	2012
Risk free interest rate	0.70%	0.64%
Expected volatility	57.60%	57.60%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

The Company recorded \$422,959 and \$320,510 of share-based compensation expense for the three months ended March 31, 2013 and 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.

There were 354,500 stock options granted under the Second Amended and Restated 2003 Stock Option and Incentive Plan (the "Second Amended 2003 Plan") during the three months ended March 31, 2013. There were 13,800 restricted stock units ("RSUs") granted to members of the Company's Board of Directors under the Second Amended 2003 Plan during the same period 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.

As of March 31, 2013, there was approximately \$3.3 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 3.0 years.

The total intrinsic value of stock options and SARs exercised during the three month periods ended March 31, 2013 and 2012 was approximately \$464,241 and \$1,192,545, respectively. Cash received from the exercise of stock options during the three-month periods ended March 31, 2013 and 2012 was \$1,097,016 and \$114,656, respectively.

There were approximately 2.0 million options and SARs outstanding under the Company's incentive plans at March 31, 2013 with a weighted-average exercise price of \$8.72 per share, an aggregate intrinsic value of approximately \$11.7 million, and a weighted-average remaining contractual term of 6.44 years.

None of the options or SARs outstanding at March 31, 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 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 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 months ended March 31, 2013 and 2012 are as follows:

	Three months ended March 31,	
	2013	2012
Shares used in the calculation of Basic earnings per share	13,406,952	13,162,824
Effect of dilutive securities:		
Stock options, SARs, RSAs, and shares held in escrow	950,158	927,122
Diluted shares used in the calculation of earnings per share	14,357,110	14,089,946

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 March 31, 2013. 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 555,001 and 380,551 shares were outstanding for the three months ended March 31, 2013 and 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:

	March 31,	December 31,
	2013	2012
Raw materials	\$ 5,990,124	\$ 6,109,807
Work-in-process	1,947,084	777,056
Finished goods	2,010,753	1,396,609
Total	\$ 9,947,961	\$ 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 March 31, 2013 and December 31, 2012 consist of the following:

	March 31, 2013			December 31, 2012		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$ 16,700,000	\$ (1,785,407)	\$ (3,217,884)	\$ 11,696,709	\$ 12,370,042	15
In-process research & development	5,502,686	(588,296)	-	4,914,390	4,980,574	Indefinite
Distributor relationships	4,700,000	(502,480)	(2,758,442)	1,439,078	1,733,453	5
Patents	1,000,000	(106,910)	(183,407)	709,683	749,166	16
Eleveess trade name	1,000,000	-	(529,938)	470,062	501,401	9
Total	\$ 28,902,686	\$ (2,983,093)	\$ (6,689,671)	\$ 19,229,922	\$ 20,334,636	

The aggregate amortization expense related to intangible assets was \$519,982 and \$516,278 for the three months ended March 31, 2013 and 2012, respectively.

Changes in the carrying value of goodwill for the three months ended March 31, 2013 were as follows:

Balance at December 31, 2012	\$9,065,891
Effect of foreign currency adjustments	(273,726)
Balance at March 31, 2013	\$8,792,165

9. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2013	December 31, 2012
Payroll and benefits	\$ 1,948,135	\$ 2,477,833
Professional fees	559,098	642,853
Clinical trial costs	134,835	102,414
SRL Research grant	82,203	110,350
Restructuring costs	310,578	933,732
Other	1,217,725	1,569,862
Total	\$ 4,252,574	\$ 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 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 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. This labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. and, as a result, 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 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. We have begun an arbitration process with Fidia in the London Court of International Arbitration to resolve the matter. Management has assessed Fidia’s claims 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.

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 March 31, 2013, the Company had an outstanding debt balance of \$9,200,000, at an interest rate of 1.53%. 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.

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 \$9,200,000 and \$9,600,000 at March 31, 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

March 31, 2013 and December 31, 2012, respectively.

12. Income Taxes

Income tax expense was \$1,903,864 and \$1,099,738 for the three months ended March 31, 2013 and 2012, respectively. The effective tax rates were 38.3% and 36.5% for the three months ended March 31, 2013 and 2012, respectively. The increase in the effective tax rate is primarily due to the applicability of a higher federal rate bracket in the current quarter combined with increases in the non-deductibility of certain expenses.

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 2012 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state 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 not otherwise subject to a valuation allowance are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at March 31, 2013 or December 31, 2012, 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 March 31, 2013. As of March 31, 2013, Fidia owns approximately 14.16% 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	Five
Raw material supply	Hyaluronic acid powder (EXPIRED)	Three
Services	Finance, administrative, security	One to Six
Accounts receivable management	Collection of trade receivables outstanding as of December 30, 2009 (EXPIRED)	Two
Marketing and Promotion	Promote Anika Srl products in Italy through Fidia sales force (TERMINATED)	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.

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 March 31,	
	2013	2012
Orthobiologics	\$ 11,283,547	\$ 10,116,845
Surgical	988,864	983,628
Dermal	241,584	501,315
Ophthalmic	928,458	1,323,994
Veterinary	1,052,036	687,546
	\$ 14,494,489	\$ 13,613,328

Product revenue by geographic location in total and as a percentage of total product revenue, for the three months ended March 31, 2013 and 2012 are as follows:

Geographic Location:	Three Months Ended March 31,			
	2013	Percentage of Revenue	2012	Percentage of Revenue
United States	\$ 11,566,779	80 %	\$ 10,390,045	76 %
Europe	1,547,914	11 %	1,770,752	13 %

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Other	1,379,796	9	%	1,452,531	11	%
Total	\$ 14,494,489	100	%	\$ 13,613,328	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 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. The remaining \$0.9 million relates to cash payments that are anticipated to occur in 2013, primarily for employee termination costs.

We made substantial progress in the first quarter of 2013 in completing the planned restructuring. During the current quarter, we sold certain previously impaired and written-off equipment resulting in a \$135,607 restructuring credit recorded during the three months ended March 31, 2013. The carrying value of the restructuring accrual approximated fair value at March 31, 2013.

The following table summarizes restructuring accrual activity for the three months ended March 31, 2013:

	2013 Restructuring Accrual		
	Employee Severance and Related Benefits	Activity Termination and Facility Closure Costs	Total
December 31, 2012	\$ 801,453	\$ 132,279	\$ 933,732
Q1 2013 Charges to Operations	-	-	-
Cash Proceeds, Disbursements	(587,662)	(43,142)	(630,804)
Write Offs and Abandonments	-	-	-
Foreign Exchange Impact	7,931	(281)	7,650
Restructuring Accrual - March 31, 2013	\$ 221,722	\$ 88,856	\$ 310,578

ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF 2. 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 expectations regarding future sales and product revenue, including geographic expansions, possible retroactive price adjustments, and expectations of unit volumes or other offsets to price reductions, for our products;
 - 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 line extensions and new products;
 - Our ability to achieve or maintain compliance with laws and regulations;
- The timing of and/or receipt of 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 activities;
- 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 orthobiologics products, including expectations regarding new products, expanded uses of existing products, new distribution partnerships, and revenue growth;
- Our intention to increase market share for our orthobiologics 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/orthobiologics product developments, clinical trials, regulatory approvals and commercial launches;

- 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 expectations regarding our existing aesthetics product line's extensions;
 - Our expectations regarding product gross margin;
- Our expectations regarding U.S. MONOVISCTM and the results of the related premarket approval ("PMA") filing with the FDA, including our submission of a PMA amendment in connection with recent discussions with the FDA following their rejection of our appeal of the non-approvable letter, and the likelihood of our obtaining such approval and/or the anticipated timing thereof;
- Our expectations regarding the commencement of a clinical trial for CINGAL™, including the expense associated therewith, and our ability to obtain regulatory approvals for CINGAL;
- 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;
 - Our ability to continue streamlining operations and improving our manufacturing activities;
 - 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 successfully complete the restructuring of Anika S.r.l., including the closing of the tissue engineering facility in Abano Treme, Italy, and manage its operation from one with losses, into a company generating profits;
 - Our abilities to effectively commercialize 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 the Merogel Injectable product; 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 technology chemically modifies 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 European Medicines Agency (“EMA”) for Advanced Therapy Medicinal Products (“ATMP”) (cell based) products that were effective January 1, 2013. The Company adopted a restructuring plan which includes a reduction-in-force of 12 people and provides 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 made substantial progress during the first quarter of 2013 in completing the planned activities. We expect to be substantially completed with the implementation of the restructuring plan during the first six months of 2013.

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 or other government-funded healthcare agencies. As of March 31, 2013, the Company’s accounts receivable from all Italian customers totaled approximately \$1.1 million, of which public hospital or agency receivables were approximately \$0.3 million, as compared to accounts receivable from all Italian customers of approximately \$3.2 million, of which public hospital or agency receivables totaled approximately \$2.4 million, at March 31, 2012.

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 January 2013, the Company submitted a new PMA amendment which is under review by the FDA. The Company continues to discuss pathways for MONOVISC approval with the FDA.

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. Preparation for the clinical trial is substantially completed and we expect to commence patient enrollment during the first half of 2013 to obtain the needed clinical data for a CE Mark submission and approval.

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; Hyalospine, an adhesion prevention gel for use after spinal surgery; Hyalobone, a bone tissue filler; and Hemostatic Patch, a resorbable hemostatic pad for bleeding control and hemostasis promotion in various surgical procedures.

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 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 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. This labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. and, as a result, 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 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. We have begun an arbitration process with Fidia in the London Court of International Arbitration to resolve the matter. Management has assessed Fidia's claims 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.

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

Anika Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,				
	2013	2012	Inc/(Dec)	Inc/(Dec)	
Product revenue	\$ 14,494,489	\$ 13,613,328	\$ 881,161	6.5	%
Licensing, milestone and contract revenue	752,522	747,332	5,190	0.7	%
Total revenue	15,247,011	14,360,660	886,351	6.2	%
Operating expenses:					
Cost of product revenue	4,841,170	6,413,481	(1,572,311)	(24.5	%)
Research & development	1,582,910	1,533,103	49,807	3.2	%
Selling, general & administrative	3,947,114	3,351,016	596,098	17.8	%
Restructuring charges	(135,607)	-	(135,607)	-	
Total operating expenses	10,235,587	11,297,600	(1,062,013)	(9.4	%)
Income from operations	5,011,424	3,063,060	1,948,364	63.6	%
Interest income (expense), net	(39,558)	(51,203)	11,645	(22.7	%)
Income before income taxes	4,971,866	3,011,857	1,960,009	65.1	%
Provision for income taxes	1,903,864	1,099,738	804,126	73.1	%
Net income	\$ 3,068,002	\$ 1,912,119	\$ 1,155,883	60.5	%
Product gross margin	9,653,319	7,199,847	2,453,472	34.1	%
Product gross margin	66.6 %	52.9 %			

Product Revenue

Product revenue for the quarter ended March 31, 2013 was \$14,494,489, an increase of 6%, as compared to \$13,613,328 for the quarter ended March 31, 2012. The first quarter increase was primarily driven by the growth of our orthobiologics franchise, as well as an increase in revenue from our veterinary product, HYVISC. The growth of the Orthobiologics franchise continues to be driven by U.S. demand for ORTHOVISC. The increase in veterinary product revenue was due to the timing of our distributor's ordering pattern. Increases in ORTHOVISC and HYVISC revenues were partially offset by a decline in Ophthalmic revenue driven by lower sales under our supply agreement with Bausch and Lomb, and a decrease in Dermal revenue due primarily to order timing on behalf of our distribution partners.

The following table presents product revenue by group for the three month periods ended March 31, 2013 and 2012:

	Three Months Ended March 31,		Increase (Decrease)	
	2013	2012	\$	%
Orthobiologics	\$ 11,283,547	\$ 10,116,845	\$ 1,166,702	11.5 %
Dermal	241,584	501,315	(259,731)	(51.8 %)
Ophthalmic	928,458	1,323,994	(395,536)	(29.9 %)
Surgical	988,864	983,628	5,236	0.5 %
Veterinary	1,052,036	687,546	364,490	53.0 %

\$ 14,494,489 \$ 13,613,328 \$ 881,161 6.5 %

Orthobiologics

The Orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 12% for the three months ended March 31, 2013, as compared to the same period in 2012. The increases were led by our ORTHOVISC sales in the U.S. First-quarter revenue from U.S. sales of ORTHOVISC increased by 12% from the same period last year. This increase reflects DePuy Mitek's continued efforts to broaden awareness and expand penetration of ORTHOVISC in both the physician and patient communities across the country.

International orthobiologics product revenue increased 9% for the three months ended March 31, 2013, as compared to the same period in 2012. This was primarily driven by an increase in Anika S.r.l. orthopedic products due to increased revenue from existing distributors and expansion into new territories. International sales of ORTHOVISC and MONOVISC remained substantially unchanged, compared to the same period in 2012, as the European economy continues to face economic challenges. In spite of the challenges, we have built strong positions in several countries such as Austria, Egypt, Turkey and Saudi Arabia. We plan to model those successes as we expand to other territories. During the first quarter of 2013, the distribution rights for Orthovisc and Monovisc in Canada were transferred to Pharmascience, resulting in an increase in product revenue. Pharmascience is a major pharmaceutical company in Canada with significant market reach, and this new relationship gives us the potential for additional growth in that market.

Dermal

Our dermal products consist of advanced wound care products and aesthetic dermal fillers. Overall, dermal product sales decreased 52% for the quarter to \$241,584, compared with revenue of \$501,315 for the same period in 2012. The decrease is related to no aesthetics product shipments in the first quarter of 2013 as a result of order timing. Anika's advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers and leading products include Hyalomatrix and Hyalofill. Outside of the U.S., we are focused on Hyalomatrix in Latin America. During the first quarter 2013, we received product approval for Hyalomatrix in Mexico, under the name HYALOMATRIXPA®, and we expect to begin product shipments to Mexico by the middle of 2013. We continue to anticipate additional Latin American approvals for our advanced wound care products later in the year and into 2014. During the quarter ended March 31, 2013, we terminated our U.S. distribution agreement with Misonix for Hyalomatrix, and we are actively seeking a new partner in the United States. For the full year 2013, we expect revenue from our dermal products to grow from 2012.

Surgical

Our surgical group consists of products used to prevent post-surgical adhesions in abdominal, spinal, and ear, nose and throat ("ENT") disorders. Sales of our surgical products increased modestly to \$988,864 for the three months ended March 31, 2013, as compared to \$983,628 in the same period last year. Sales of our ENT products almost doubled from the first quarter last year. This was primarily the result of our resuming shipments of Merogel Injectable to Medtronic following the resolution of a labeling error on the product's packaging. Medtronic re-launched the compliant version of Merogel Injectable in the U.S. in February 2013. The increase in ENT revenue was partially offset by the decreases in our anti-adhesion products including Hyalobarrier and INCERT. Such decreases were primarily due to order timing, which we expect to recover in future quarters.

Ophthalmic

Our ophthalmic business consists of HA viscoelastic products used in ophthalmic surgery. Ophthalmic product sales decreased 30% to \$928,458 for the three months ended March 31, 2013, as compared to the same period in 2012 related to sales to Bausch and Lomb. As previously disclosed, we expect ophthalmic revenue to be lower in 2013

compared to 2012 under the terms of the current Bausch & Lomb supply agreement.

Veterinary

Veterinary revenue from HYVISC increased 53% to \$1,052,036 for the three months ended March 31, 2013. The increase for the three-month period was primarily due to order timing by our distribution partner, Boehringer Ingelheim Vetmedica. We expect overall HYVISC revenue for 2013 to be at a comparable level to 2012's revenue for this product.

Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three months ended March 31, 2013 was \$752,522 as compared to \$747,332 during the same period 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. ORTHOVISC 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. 2013 will be the final year for the ratable recognition of these milestone payments. In November 2012, Depuy Mitek exercised its option and extended the distribution agreement for an additional five years through December 2018.

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 is being recognized ratably over the fifteen year term of the agreement. The Company is entitled to receive additional payments from DePuy Mitek, following FDA approval and the mutual decision to launch MONOVISC, as well as payments related to future regulatory, clinical and sales milestones.

Product gross profit and margin

Product gross profit for the three months ended March 31, 2013 and 2012 was \$9,653,319 and \$7,199,847, or 67% and 53% of product revenue, respectively. The increase in product gross profit and margin for the quarter ended March 31, 2013, as compared to the same quarter in the previous year, was primarily due to the elimination of duplicate manufacturing facility costs, manufacturing process improvements and scale efficiencies at our Bedford, Massachusetts facility, and favorable product sales mix in the quarter. 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 the future mix of our product sales.

Research and development

Research and development expenses increased 3% for the three months ended March 31, 2013 to \$1,582,910 from \$1,533,103 for the same period in the prior year. The increase was primarily due to start-up expenses related to the planned CINGAL clinical trial in the current year. The modest increase in R&D spending for the first quarter was due to non-recurring development expenses in same period last year for Hyalograft C autograft and Hyalospine. Research and development expenses are expected to increase in future quarters with increased expenditures planned on clinical trials for CINGAL, as well as spending on further development of Anika's pipeline of new products and new products expected to be developed based on our technology assets.

Selling, general and administrative

Selling, general and administrative ("SG&A") expenses increased 18% for the three months ended March 31, 2013 to \$3,947,114 from \$3,351,016 for the same period in the prior year. The increase in expense for the quarter was primarily due to personnel and external professional spending.

Restructuring Charge

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, which were effective January 1, 2013. We made substantial progress in the first quarter of 2013 in completing the planned restructuring. During the current quarter, we sold certain previously impaired and written-off equipment resulting in a \$135,607 restructuring credit recorded during the three months ended March 31, 2013.

Interest income (expense), net

Net interest expense was \$39,558 and \$51,203 for the three months ended March 31, 2013 and 2012, respectively. The decrease in interest expense for the quarter is primarily due to a lower level of interest-bearing debt in 2013 as compared to the same period in 2012.

Income taxes

Provisions for income taxes were \$1,903,864 and \$1,099,738 for the three months ended March 31, 2013 and 2012, based on effective tax rates of 38.3% and 36.5%, respectively. The increase in the effective tax rate for the three-month period ended March 31, 2013, as compared to the same period in 2012, is primarily due to the applicability of a higher federal rate bracket in the current quarter combined with increases in the non-deductibility of certain expenses.

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 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 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 not otherwise subject to a valuation allowance are realizable on a “more likely than not” basis. As such, we have not recorded a valuation allowance at March 31, 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 funded our cash requirements from operations, available cash and investments on hand, and debt. Cash and cash equivalents totaled approximately \$51.0 million and \$44.1 million at March 31, 2013 and December 31, 2012, respectively. Working capital totaled approximately \$68.0 million at March 31, 2013 and \$62.9 million at December 31, 2012, respectively. The Company believes it has adequate financial resources to support its business over the next twelve months.

Cash provided by operating activities was \$6,068,854 for the three months ended March 31, 2013 as compared to cash used in operating activities of \$1,689,649 for the same period in the prior year. This increase in cash provided by operations during the three months ended March 31, 2013 was primarily due to a \$1.2 million increase in net income combined with a \$6.0 million decrease in accounts receivable, as compared to the same period in 2012.

Cash provided by investing activities was \$99,805 for the three months ended March 31, 2013, as compared to cash used in investing activities of \$224,059 for the same period in 2012. The increase in cash provided by investing activities is a result of the proceeds received from the sale of property and equipment relating to our reorganization at Anika S.r.l., partially offset by capital expenditures and related projects associated with maintaining our Bedford facility.

Cash provided by financing activities was \$761,658 for the three months ended March 31, 2013 as compared to cash provided by financing activities of \$108,732 for the same period in 2012. The increase in cash provided is attributable to an increase in funds received due to employee stock option exercises, combined with their associated income tax benefits received during the first three 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 three months ended March 31, 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 \$9,200,000 as of March 31, 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.

We do not have any special purpose entities or off-balance sheet financing arrangements.

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, 2012.

As of March 31, 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 three months ended March 31, 2013. 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 \$749,450 during the first three months of 2013. We currently do not seek to hedge this exposure to fluctuations in exchange rates.

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 March 31, 2013, we were subject to interest rate risk on \$9.2 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 March 31, 2013, we would have a decrease in future annual cash flow of approximately \$84,000 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 first three months of fiscal year 2013 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 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 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. This labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. and, as a result, 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 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. We have begun an arbitration process with Fidia in the London Court of International Arbitration to resolve the matter. Management has assessed Fidia's claims 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.

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

ITEM 1A. RISK FACTORS

To our knowledge, there have been no material changes to the risk factors described in “Part I., Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2012, 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, 2012, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

ITEM 6. EXHIBITS

Exhibit No.	Description
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Sylvia Cheung pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32)	Section 1350 Certifications
**32.1	Certification of Charles H. Sherwood, Ph.D. and Sylvia Cheung, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	XBRL
101§	The following materials from Anika Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, as filed with the SEC on May 4, 2013, formatted in XBRL (eXtensible Business Reporting Language), as follows:
	<ul style="list-style-type: none"> i. Condensed Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012 ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three Months Ended March 31, 2013 and March 31, 2012 (unaudited) iii. Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2013 and March 31, 2012 (unaudited) iv. Notes to Condensed Consolidated Financial Statements (unaudited)

* 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.

May 6, 2013

By:

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