

ANIKA THERAPEUTICS INC
Form 10-Q
August 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 June 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer
(Do not check if a smaller reporting company) Smaller reporting company

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

As of August 1, 2013, there were 13,662,136 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)

	June 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$54,140,459	\$44,067,477
Accounts receivable, net of reserves of \$332,148 and \$337,459 at June 30, 2013 and December 31, 2012, respectively	19,065,386	21,462,481
Inventories	10,357,798	8,283,472
Current portion deferred income taxes	1,989,422	2,031,583
Prepaid expenses and other	920,873	1,539,477
Total current assets	86,473,938	77,384,490
Property and equipment, at cost	51,618,726	52,376,013
Less: accumulated depreciation	(17,772,147)	(17,263,032)
	33,846,579	35,112,981
Long-term deposits and other	154,050	171,053
Intangible assets, net	18,996,886	20,334,636
Goodwill	8,923,197	9,065,891
Total Assets	\$148,394,650	\$142,069,051
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,699,678	\$2,341,838
Accrued expenses	4,503,551	5,837,044
Deferred revenue	1,527,917	2,875,067
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	1,370,172	1,798,669
Total current liabilities	11,701,318	14,452,618
Other long-term liabilities	1,264,427	1,541,124
Long-term deferred revenue	2,069,444	2,152,778
Deferred tax liability	6,725,622	6,997,397
Long-term debt	7,200,000	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 June 30, 2013 and December 31, 2012, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 14,017,280 and 13,866,060 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	140,173	138,659
Additional paid-in-capital	67,385,076	65,431,424
Accumulated currency translation adjustment	(3,063,985)	(2,654,630)
Retained earnings	54,972,575	46,009,681
Total stockholders' equity	119,433,839	108,925,134
Total Liabilities and Stockholders' Equity	\$148,394,650	\$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 June		Six Months Ended June 30,	
	2013	2012	2013	2012
Product revenue	\$20,067,407	\$18,882,277	\$34,561,896	\$32,495,605
Licensing, milestone and contract revenue	760,970	742,492	1,513,492	1,489,824
Total revenue	20,828,377	19,624,769	36,075,388	33,985,429
Operating expenses:				
Cost of product revenue	6,311,332	8,084,226	11,152,502	14,497,707
Research & development	1,829,052	1,298,170	3,411,962	2,831,273
Selling, general & administrative	3,400,679	4,108,503	7,347,793	7,459,519
Restructuring charges	(111,178)	-	(246,785)	-
Total operating expenses	11,429,885	13,490,899	21,665,472	24,788,499
Income from operations	9,398,492	6,133,870	14,409,916	9,196,930
Interest income (expense), net	(36,381)	(49,129)	(75,939)	(100,332)
Income before income taxes	9,362,111	6,084,741	14,333,977	9,096,598
Provision for income taxes	3,467,219	2,347,873	5,371,083	3,447,611
Net income	\$5,894,892	\$3,736,868	\$8,962,894	\$5,648,987
Basic net income per share:				
Net income	\$0.44	\$0.28	\$0.67	\$0.43
Basic weighted average common shares outstanding	13,510,573	13,262,023	13,459,049	13,212,424
Diluted net income per share:				
Net income	\$0.40	\$0.26	\$0.62	\$0.39
Diluted weighted average common shares outstanding	14,578,927	14,443,794	14,484,978	14,302,439
Net income	\$5,894,892	\$3,736,868	\$8,962,894	\$5,648,987
Other comprehensive income				
Foreign currency translation adjustment	340,095	(1,600,204)	(409,355)	(843,743)
Comprehensive income	\$6,234,987	\$2,136,664	\$8,553,539	\$4,805,244

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)

	Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net income	\$8,962,894	\$5,648,987
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,270,895	2,182,129
Stock-based compensation expense	788,326	633,073
Deferred income taxes	(269,149)	14,036
Provision for doubtful accounts	-	135,353
Provision for inventory	229,885	164,300
Tax benefit from exercise of stock options	(7,596)	(400,325)
Changes in operating assets and liabilities:		
Accounts receivable	1,796,522	(892,265)
Inventories	(2,324,269)	(3,713,817)
Prepaid expenses, other current and long-term assets	703,303	590,614
Long-term deposits and other	16,998	16,997
Accounts payable	878,228	(170,035)
Accrued expenses	(1,270,885)	(920,168)
Deferred revenue	(1,430,484)	(1,433,334)
Income taxes payable	(440,210)	1,679,579
Other long-term liabilities	(271,532)	(335)
Net cash provided by operating activities	9,632,926	3,534,789
Cash flows from investing activities:		
Proceeds from sales of assets	246,785	-
Purchase of property and equipment, net	(109,871)	(1,145,493)
Net cash provided by (used in) investing activities	136,914	(1,145,493)
Cash flows from financing activities:		
Principal payments on debt	(800,000)	(800,000)
Proceeds from exercise of stock options	1,127,875	147,033
Tax benefit from exercise of stock options	7,596	400,325
Net cash provided by (used in) financing activities	335,471	(252,642)
Exchange rate impact on cash	(32,329)	(4,268)
Increase in cash and cash equivalents	10,072,982	2,132,386
Cash and cash equivalents at beginning of period	44,067,477	35,777,222
Cash and cash equivalents at end of period	\$54,140,459	\$37,909,608

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

ANIKA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business

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

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with the U.S. Food and Drug Administration (“FDA”) and foreign regulations and approval requirements as well as the ability to grow the Company’s business.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) and in accordance with accounting principles generally accepted in the United States (“U.S.”). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. The year-end consolidated balance sheet is derived from our audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of June 30, 2013 and the results of its operations for the three and six months ended June 30, 2013 and 2012 and cash flows for the six months ended June 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 periods ended June 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 six months ended June 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 six months ended June 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 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.

Cash equivalents in money market accounts measured and recorded at fair value on a recurring basis was \$34,264,268 at June 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 six months ended June 30, 2013 and the six months ended June 30, 2012 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,	
	2013	2012
Risk free interest rate	0.65%	-
Expected volatility	57.60%	-
Expected lives (years)	4	-
Expected dividend yield	0.00%	-
	Six Months Ended June 30,	
	2013	2012
Risk free interest rate	0.61% - 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 \$365,367 and \$788,326 of share-based compensation expense for the three and six months ended June 30, 2013, respectively, for equity compensation awards. The Company recorded \$312,563 and \$633,073 of share-based compensation expense for the three and six months ended June 30, 2012. 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.

6

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 20,000 stock options granted under the 2003 Plan during the three months ended June 30, 2013. There were 374,500 stock options granted under the Plan during the six months ended June 30, 2013. There were no restricted stock units (“RSUs”) granted to members of the Company’s Board of Directors during the three months ended June 30, 2013. There were 13,800 RSUs 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.

As of June 30, 2013, there was approximately \$3.0 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 2.9 years.

The total intrinsic value of stock options and SARs exercised during the six-month periods ended June 30, 2013 and 2012 was \$599,010 and \$1,241,759, respectively. Cash received from the exercise of stock options during the three and six-month periods ended June 30, 2013 was \$30,859 and \$1,127,875, respectively. Cash received from the exercise of stock options during the three and six-month periods ended June 30, 2012 was \$32,377 and \$147,033, respectively.

There were approximately 1.9 million options and SARs outstanding under the Company’s incentive plans at June 30, 2013 with a weighted-average exercise price of \$8.60 per share, an aggregate intrinsic value of approximately \$16.2 million, and a weighted-average remaining contractual term of 6.27 years.

None of the options or SARs outstanding at June 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 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 and six months ended June 30, 2013 and 2012 are as follows:

	Three months ended June	Six months ended June 30,
	30,	

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

	2013	2012	2013	2012
Shares used in the calculation of Basic earnings per share	13,510,573	13,262,023	13,459,049	13,212,424
Effect of dilutive securities:				
Stock options, SARs, RSAs, and shares held in escrow	1,068,354	1,181,771	1,025,929	1,090,015
Diluted shares used in the calculation of earnings per share	14,578,927	14,443,794	14,484,978	14,302,439

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 June 30, 2013. These 500,000 shares are included in the diluted potential common shares but are excluded from the basic earnings per share calculation.

Equity awards of 469,618 and 459,969 shares were outstanding for the three and six months ended June 30, 2013, respectively, but were not included in the computation of diluted earnings per share because the awards’ impact on earnings per share was anti-dilutive. Equity awards of 99,245 and 126,124 shares were outstanding for the three and six months ended June 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:

	June 30, 2013	December 31, 2012
Raw materials	\$ 6,160,860	\$ 6,109,807
Work-in-process	2,016,882	777,056
Finished goods	2,180,056	1,396,609
Total	\$ 10,357,798	\$ 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 June 30, 2013 and December 31, 2012 consist of the following:

	June 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	\$(1,609,247)	\$(3,472,667)	\$11,618,086	\$12,370,042	15
In-process research & development	5,502,686	(512,634)	-	4,990,052	4,980,574	Indefinite
Distributor relationships	4,700,000	(483,620)	(2,972,514)	1,243,866	1,733,453	5
Patents	1,000,000	(96,203)	(197,640)	706,157	749,166	16
Ele vess trade name	1,000,000	-	(561,275)	438,725	501,401	9
Total	\$28,902,686	\$(2,701,704)	\$(7,204,096)	\$18,996,886	\$20,334,636	

The aggregate amortization expense related to intangible assets was \$514,425 and \$506,706 for the three months ended June 30, 2013 and 2012, respectively. The aggregate amortization expense for the six months ended June 30, 2013 and 2012, was \$1,034,408 and \$1,022,984, respectively.

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

	For the three months ended: June 30, 2013	For the six months ended: June 30, 2013
Balance, beginning	\$ 8,792,165	\$ 9,065,891
Effect of foreign currency adjustments	131,032	(142,694)
Balance, ending	\$ 8,923,197	\$ 8,923,197

9. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2013	December 31, 2012
Payroll and benefits	\$ 2,162,634	\$ 2,477,833
Professional fees	469,991	642,853
Clinical trial costs	67,767	102,414
Restructuring costs	283,063	933,732
Other	1,520,096	1,680,212
Total	\$ 4,503,551	\$ 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 related 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 June 30, 2013, the Company had an outstanding debt balance of \$8,800,000, at an interest rate of 1.48%. 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 \$8,800,000 and \$9,600,000 at June 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 June 30, 2013 and December 31, 2012, respectively.

12. Income Taxes

Provisions for income taxes were \$3,467,219 and \$5,371,083 for the three and six-month periods ended June 30, 2013, respectively, based on effective tax rates of 37.0 % and 37.5 %. Provisions for income taxes were \$2,347,873 and \$3,447,611 for the three and six-month periods ended June 30, 2012, respectively, based on effective tax rates of 38.6% and 37.9%. The decrease in the effective tax rates for the periods ended 2013, as compared to the same periods in the previous year, are primarily due to increases in anticipated tax credits and subsidiary earnings at a lower tax rate.

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 are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at June 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 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 June 30, 2013. As of June 30, 2013, Fidia owns approximately 14.2% of the outstanding shares of the Company.

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

10

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)
Services	Finance, administrative, security and other	One to Six
Accounts receivable management	Collection of trade receivables outstanding as of December 30, 2009	(EXPIRED)
Marketing and promotion	Promote Anika Srl products in Italy through Fidia sales force	(TERMINATED)

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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Orthobiologics	\$ 16,506,226	\$ 10,903,364	\$ 27,789,773	\$ 21,020,209
Dermal	557,059	155,735	798,643	657,051
Surgical	1,830,022	1,464,505	2,818,886	2,448,133
Ophthalmic	464,340	5,299,732	1,392,798	6,623,726
Veterinary	709,760	1,058,941	1,761,796	1,746,486
	\$ 20,067,407	\$ 18,882,277	\$ 34,561,896	\$ 32,495,605

Total revenue by geographic location and as a percentage of total revenue, for the three and six months ended June 30, 2013 and 2012 are as follows:

Geographic Location:	Three Months Ended June 30,		2012	
	2013	Percentage of	Revenue	Percentage of
	Revenue	Revenue	Revenue	Revenue
United States	\$ 15,482,068	74 %	\$ 16,728,331	85 %
Europe	1,986,195	10 %	1,128,126	6 %
Other	3,360,114	16 %	1,768,312	9 %
Total	\$ 20,828,377	100 %	\$ 19,624,769	100 %

Geographic Location:	Six Months Ended June 30,		2012	
	2013	Percentage of	Revenue	Percentage of
	Revenue	Revenue	Revenue	Revenue
United States	\$ 27,765,515	77 %	\$ 27,835,044	82 %
Europe	3,569,963	10 %	2,929,543	9 %
Other	4,739,910	13 %	3,220,842	9 %
Total	\$ 36,075,388	100 %	\$ 33,985,429	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 six months ending June 30, 2013 in completing the planned restructuring. We sold certain previously impaired and written-off equipment, resulting in restructuring credit of \$111,178 and \$246,785 in the three and six months ended June 30, 2013, respectively. The carrying value of the restructuring accrual approximated fair value at June 30, 2013.

The following table summarizes restructuring accrual activity for the six months ended June 30, 2013:

	Restructuring Accrual Activity		
	Employee Severance and Related Benefits	Termination and Facility Closure Costs	Total
December 31, 2012	\$ 801,453	\$ 132,279	\$ 933,732
Charges to Operations	-	-	-
Cash Proceeds, Disbursements	(613,870)	(45,240)	(659,110)
Write Offs and Abandonments	-	-	-
Foreign Exchange Impact	8,422	19	8,441
June 30, 2013	\$ 196,005	\$ 87,058	\$ 283,063

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 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 and changes of current, new or potential products, and any limitations on such approvals and/ changes;

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, 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 license our aesthetics product to new distribution partners domestically and internationally; 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 HYDRELLE™/ELEVESST™ products and the timing thereof;

Our expectations regarding our existing aesthetics product line's extensions;

Our expectations regarding product gross margin and profit;

Our expectations regarding U.S. MONOVISCTM and the results of the related premarket approval (“PMA”) filing with the FDA, including our 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 completion of CINGAL™ clinical trial, 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 and general business operations;

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 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 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 are substantially completed with the implementation of the restructuring plan as of June 30, 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 June 30, 2013, the Company’s accounts receivable from all Italian customers totaled approximately \$1.2 million, of which public hospital or agency receivables were approximately \$0.3 million, as compared to accounts receivable from all Italian customers of approximately \$2.6 million, of which public hospital or agency receivables totaled approximately \$1.6 million, at June 30, 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 February 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. During the second quarter of 2013, we commenced the clinical trial 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 related 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.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Results of Operations

Three and Six Months Ended June 30, 2013 Compared to the Three and Six Months Ended June 30, 2012

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	\$ Inc/(Dec)	% Inc/(Dec)	2013	2012	\$ Inc/(Dec)	% Inc/(Dec)
Product revenue	\$20,067,407	\$18,882,277	\$1,185,130	6 %	\$34,561,896	\$32,495,605	\$2,066,291	6 %
Licensing, milestone and contract revenue	760,970	742,492	18,478	2 %	1,513,492	1,489,824	23,668	2 %
Total revenue	20,828,377	19,624,769	1,203,608	6 %	36,075,388	33,985,429	2,089,959	6 %
Operating expenses:								
Cost of product revenue	6,311,332	8,084,226	(1,772,894)	(22 %)	11,152,502	14,497,707	(3,345,205)	(23 %)
Research & development	1,829,052	1,298,170	530,882	41 %	3,411,962	2,831,273	580,689	21 %
Selling, general & administrative	3,400,679	4,108,503	(707,824)	(17 %)	7,347,793	7,459,519	(111,726)	(1 %)
Restructuring charges	(111,178)	-	(111,178)	N/M	(246,785)	-	(246,785)	N/M
Total operating expenses	11,429,885	13,490,899	(2,061,014)	(15 %)	21,665,472	24,788,499	(3,123,027)	(13 %)
Income from operations	9,398,492	6,133,870	3,264,622	53 %	14,409,916	9,196,930	5,212,986	57 %
Interest income (expense), net	(36,381)	(49,129)	12,748	(26 %)	(75,939)	(100,332)	24,393	(24 %)
Income before income taxes	9,362,111	6,084,741	3,277,370	54 %	14,333,977	9,096,598	5,237,379	58 %
Provision for income taxes	3,467,219	2,347,873	1,119,346	48 %	5,371,083	3,447,611	1,923,472	56 %
Net income	\$5,894,892	\$3,736,868	\$2,158,024	58 %	\$8,962,894	\$5,648,987	\$3,313,907	59 %
Product gross profit	13,756,075	10,798,051	2,958,024	27 %	23,409,394	17,997,898	5,411,496	30 %
Product gross margin	69 %	57 %			68 %	55 %		

Product Revenue

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Product revenue for the quarter ended June 30, 2013 was \$20,067,407, an increase of 6%, as compared to \$18,882,277 for the quarter ended June 30, 2012. Product revenue for the six months ended June 30, 2013 was \$34,561,896, an increase of 6%, as compared to \$32,495,605 for the six months ended June 30, 2012. The second quarter increase was primarily driven by a strong quarter for our orthobiologics franchise, in particular the Orthovisc product, both domestically and internationally, which was offset by the anticipated decrease in Ophthalmic sales.

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

	Three Months Ended June 30,		Increase (Decrease)	
	2013	2012	\$	%
Orthobiologics	\$ 16,506,226	\$ 10,903,364	\$ 5,602,862	51 %
Dermal	557,059	155,735	401,324	258 %
Surgical	1,830,022	1,464,505	365,517	25 %
Ophthalmic	464,340	5,299,732	(4,835,392)	(91 %)
Veterinary	709,760	1,058,941	(349,181)	(33 %)
	\$ 20,067,407	\$ 18,882,277	\$ 1,185,130	6 %

	Six Months Ended June 30,		Increase (Decrease)	
	2013	2012	\$	%
Orthobiologics	\$ 27,789,773	\$ 21,020,209	\$ 6,769,564	32 %
Dermal	798,643	657,051	141,592	22 %
Surgical	2,818,886	2,448,133	370,753	15 %
Ophthalmic	1,392,798	6,623,726	(5,230,928)	(79 %)
Veterinary	1,761,796	1,746,486	15,310	1 %
	\$ 34,561,896	\$ 32,495,605	\$ 2,066,291	6 %

Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 51% and 32% for the three and six months ended June 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 the Middle East. As previously disclosed, we expect joint health product revenue to increase in 2013 as compared to 2012, both domestically and internationally.

Dermal

Our dermal franchise consist of advanced wound care products and aesthetic dermal fillers. Overall, dermal product sales increased 258% and 22% for the three and six-month periods ended June 30, 2013, respectively, to \$557,059 and \$798,643, driven by increase in advanced wound care product revenue in Europe and Latin America, and higher sales of our aesthetic product to our international distributors due to 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. During the first quarter of 2013, we terminated our U.S. distribution agreement with Misonix for Hyalomatrix. 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, spinal, and ear, nose and throat ("ENT") disorders. Sales of our surgical products increased 25% and 15% to \$1,830,022 and \$2,818,886 for the three and six-month periods ended June 30, 2013, respectively, as compared to the same periods in 2012. Our anti-adhesion products include Hyalobarrier and INCERT. The increases in both three and six-month periods ended June 30, 2013 were primarily due to higher Hyalobarrier revenue in Europe. Sales of our ENT products sold through our worldwide partner, Medtronic, increased 11% for the six-month period ended June 30, 2013, as compared to the same period in the prior year, primarily due to 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 91% and 79% to \$464,340 and \$1,392,798 for the three and six month-periods ended June 30, 2013, respectively, as compared to the same periods in 2012. The decreases were primarily attributable to decreased sales to B&L. During the second quarter of 2012, we had approximately \$5 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 compared to 2012, under the terms of the current Bausch & Lomb supply agreement.

Veterinary

Veterinary revenue from HYVISC decreased 33% to \$709,760 and increased 1% to \$1,761,796 for the three and six-month periods ended June 30, 2013, respectively. 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 2012's revenue for this product.

Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three and six-month periods ended June 30, 2013 was \$760,970 and \$1,513,492, respectively, as compared to \$742,492 and \$1,489,824, 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 six-month periods ended June 30, 2013 was \$13,756,075 and \$23,409,394, or 69% and 68% of product revenue for each period, respectively. Product gross profit for the three and six-month periods ended June 30, 2012 was \$10,798,051 and \$17,997,898, or 57% and 55% of product revenue for each period, respectively. The increase in product gross profit for the three and six-month periods ended June 30, 2013, respectively, as compared to the same periods in 2012, is directly attributable to an overall increase in product volume, 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 non-profitable 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 six-month periods ended June 30, 2013 were \$1,829,052 and \$3,411,962, 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 six month periods ended June 30, 2013 were \$3,400,679 and \$7,347,793 respectively, representing 16% and 20% of total revenue. SG&A expenses decreased for both the three and six-month periods ended June 30, 2013 as compared to the same periods in 2012, primarily driven by the Company’s ongoing cost reduction initiatives.

Interest income (expense), net

Net interest expense was \$36,381 and \$75,939 for the three and six-month periods ended June 30, 2013, respectively. Net interest expense decreased for both the three and six-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 \$3,467,219 and \$5,371,083 for the three and six-month periods ended June 30, 2013, based on effective tax rates of 37.0 % and 37.5%, respectively. Provisions for income taxes were \$2,347,873 and \$3,447,611 for the three and six-month periods ended June 30, 2012, respectively, based on effective tax rates of 38.6% and 37.9%. 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 subsidiary earnings at a lower tax rate.

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 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 June 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 funded our cash requirements from operations, available cash and investments on hand, and debt. Cash and cash equivalents totaled approximately \$54.1 million and \$44.1 million at June 30, 2013 and December 31, 2012, respectively. Working capital totaled approximately \$74.8 million at June 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 \$9,632,926 for the six months ended June 30, 2013 as compared to cash provided by operating activities of \$3,534,789 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 requirements, as compared to the same period in 2012.

Cash provided by investing activities was \$136,914 for the six months ended June 30, 2013 as compared to cash used in investing activities of \$1,145,493 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 \$335,471 for the six months ended June 30, 2013, as compared to cash used in financing activities of \$252,642 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 six 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 six months ended June 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 \$8,800,000 as of June 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 June 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 six months ended June 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 an unfavorable currency translation adjustment of \$409,355 during the first six months of 2013.

Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of June 30, 2013, we were subject to interest rate risk on \$8.8 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 June 30, 2013, we would have a decrease in future annual cash flow of approximately \$80,000 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 June 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 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 related 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 June 30, 2013, as filed with the SEC on August 5, 2013, formatted in XBRL (eXtensible Business Reporting Language), as follows:
i.	Condensed Consolidated Balance Sheets as of June 30, 2013 (unaudited) and December 31, 2012
ii.	Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Six Months Ended June 30, 2013 and June 30, 2012 (unaudited)
iii.	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2013 and June 30, 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.

August 6, 2013

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