

ANIKA THERAPEUTICS INC  
Form 10-Q  
August 07, 2012

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended June 30, 2012

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

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

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Commission File Number 000-21326

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

Massachusetts  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

01730  
(Zip Code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,

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or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="radio"/>	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="radio"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="radio"/>
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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes  No

As of August 3, 2012, there were 13,802,590 outstanding shares of Common Stock, par value \$.01 per share.

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PART I: FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

## Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets  
(unaudited)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,909,608	\$ 35,777,222
Accounts receivable, net of reserves of \$457,300 and \$334,473 at June 30, 2012 and December 31, 2011, respectively	17,694,097	17,307,786
Inventories	10,776,788	7,302,483
Current portion deferred income taxes	1,918,926	1,918,926
Prepaid expenses and other	1,299,596	1,831,127
Total current assets	69,599,015	64,137,544
Property and equipment, at cost	51,920,745	50,850,630
Less: accumulated depreciation	(15,499,638 )	(14,380,752 )
	36,421,107	36,469,878
Long-term deposits and other	221,485	205,042
Intangible assets, net	21,506,474	23,148,563
Goodwill	8,627,518	8,883,407
Total Assets	\$ 136,375,599	\$ 132,844,434

## LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 3,941,436	\$ 4,299,680
Accrued expenses	4,275,574	5,321,594
Deferred revenue	2,866,667	2,866,667
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	2,530,386	450,482
Total current liabilities	15,214,063	14,538,423
Other long-term liabilities	1,535,140	1,548,652
Long-term deferred revenue	3,586,106	5,019,440
Deferred tax liability	6,491,837	7,375,141
Long-term debt	8,800,000	9,600,000
Commitments and contingencies (Note 10)	-	-
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 13,765,996 and 13,630,607 shares issued and outstanding at	137,659	136,305

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June 30, 2012 and December 31, 2011, respectively

Additional paid-in-capital	64,620,510	63,441,433
Accumulated currency translation adjustment	(3,910,924 )	(3,067,181 )
Retained earnings	39,901,208	34,252,221
Total stockholders' equity	100,748,453	94,762,778
Total Liabilities and Stockholders' Equity	\$ 136,375,599	\$ 132,844,434

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Product revenue	\$ 18,882,277	\$ 15,414,681	\$ 32,495,605	\$ 26,474,840
Licensing, milestone and contract revenue	742,492	726,171	1,489,824	1,403,691
Total revenue	19,624,769	16,140,852	33,985,429	27,878,531
Operating expenses:				
Cost of product revenue	8,084,226	6,655,804	14,497,707	12,260,366
Research & development	1,298,170	1,574,155	2,831,273	3,106,820
Selling, general & administrative	4,108,503	4,233,316	7,459,519	8,277,090
Total operating expenses	13,490,899	12,463,275	24,788,499	23,644,276
Income from operations	6,133,870	3,677,577	9,196,930	4,234,255
Interest income (expense), net	(49,129 )	(45,281 )	(100,332 )	(86,202 )
Income before income taxes	6,084,741	3,632,296	9,096,598	4,148,053
Provision for income taxes	2,347,873	1,349,655	3,447,611	1,541,001
Net income	\$ 3,736,868	\$ 2,282,641	\$ 5,648,987	\$ 2,607,052
Basic net income per share:				
Net income	\$ 0.28	\$ 0.18	\$ 0.43	\$ 0.21
Basic weighted average common shares outstanding	13,262,023	12,725,216	13,212,424	12,707,143
Diluted net income per share:				
Net income	\$ 0.26	\$ 0.17	\$ 0.39	\$ 0.19
Diluted weighted average common shares outstanding	14,443,794	13,739,836	14,302,439	13,741,337
Net income	\$ 3,736,868	\$ 2,282,641	\$ 5,648,987	\$ 2,607,052
Other comprehensive income				
Foreign currency translation adjustment	(1,600,204 )	595,200	(843,743 )	2,344,862
Comprehensive income	\$ 2,136,664	\$ 2,877,841	\$ 4,805,244	\$ 4,951,914

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,	
	2012	2011
Cash flows from operating activities:		
Net income	\$5,648,987	\$2,607,052
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,182,129	1,940,827
Stock-based compensation expense	633,073	582,307
Deferred income taxes	14,036	828,703
Provision for doubtful accounts	135,353	-
Provision for inventory	164,300	537,657
Tax benefit from exercise of stock options	(400,325 )	-
Changes in operating assets and liabilities:		
Accounts receivable	(892,265 )	(1,618,730 )
Inventories	(3,713,817 )	(536,642 )
Prepaid expenses, other current and long-term assets	590,614	(366,213 )
Long-term deposits and other	16,997	16,998
Accounts payable	(170,035 )	(2,642,810 )
Accrued expenses	(920,168 )	(510,426 )
Deferred revenue	(1,433,334 )	(1,342,473 )
Income taxes payable	1,679,579	411,843
Other long-term liabilities	(335 )	(18,592 )
Net cash provided by (used in) operating activities	3,534,789	(110,499 )
Cash flows from investing activities:		
Purchase of property and equipment	(1,145,493 )	(655,784 )
Net cash used in investing activities	(1,145,493 )	(655,784 )
Cash flows from financing activities:		
Principal payments on debt	(800,000 )	(800,000 )
Proceeds from exercise of stock options	147,033	151,767
Tax benefit from exercise of stock options	400,325	-
Net cash used in financing activities	(252,642 )	(648,233 )
Exchange rate impact on cash	(4,268 )	41,613
Increase (decrease) in cash and cash equivalents	2,132,386	(1,372,903 )
Cash and cash equivalents at beginning of period	35,777,222	28,201,932
Cash and cash equivalents at end of period	\$37,909,608	\$26,829,029

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, 2012 and the results of its operations for the three and six months ended June 30, 2012 and 2011 and cash flows for the six months ended June 30, 2012 and 2011.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company’s annual financial statements filed with its Annual Report on Form 10-K for the year ended December 31, 2011. There have been no changes in our significant accounting policies for the three and six months ended June 30, 2012 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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

3. Recent Accounting Pronouncements Issued or Adopted

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

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

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

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



#### 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:

	June 30, 2012			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$ 20,263,766	\$ -	\$ -	\$ 20,263,766

  

	December 31, 2011			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$ 20,263,766	\$ -	\$ -	\$ 20,263,766

#### 5. Equity Incentive Plan

The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Fair value of restricted stock is measured by the grant-date price of the Company's shares. The fair value of each stock option award during the six months ended June 30, 2012 and the three and six months ended June 30, 2011 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,		
	2012	2011	
Risk free interest rate	N/A	1.19	%
Expected volatility	N/A	57.60	%
Expected lives (years)	N/A	4	
Expected dividend yield	N/A	0.00	%

Six Months Ended  
June 30,

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	2012		2011	
Risk free interest rate	0.64	%	1.19% - 1.51	%
Expected volatility	57.60	%	57.60	%
Expected lives (years)	4		4	
Expected dividend yield	0.00	%	0.00	%

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The Company recorded \$312,563 and \$633,073 of share-based compensation expense for the three and six months ended June 30, 2012, respectively, for equity compensation awards. The Company recorded \$282,032 and \$582,307 of share-based compensation expense for the three and six months ended June 30, 2011. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the respective employees.

There were no stock options granted under the Second Amended and Restated 2003 Stock Option and Incentive Plan (the "Plan") during the three months ended June 30, 2012. There were 119,000 stock options granted under the Plan during the six months ended June 30, 2012. There were no restricted stock units ("RSUs") granted to members of the Company's Board of Directors during the three months ended June 30, 2012. There were 16,480 RSUs granted to members of the Company's Board of Directors under the Plan during the six months ended June 30, 2012. The stock options and RSUs granted to employees and directors become exercisable or vest ratably over four years from the date of grant.

As of June 30, 2012, there was approximately \$2.5 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 2.3 years.

The total intrinsic value of stock options and SARs exercised during the six-month periods ended June 30, 2012 and 2011 was \$1,241,759 and \$628,077, 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. Cash received from the exercise of stock options during the three and six-month periods ended June 30, 2011 was \$122,825 and \$151,767, respectively.

There were approximately 2.0 million options and SARs outstanding under the Company's incentive plans at June 30, 2012 with a weighted-average exercise price of \$7.72 per share, an aggregate intrinsic value of approximately \$11.9 million, and a weighted-average remaining contractual term of 6.55 years.

None of the options or SARs outstanding at June 30, 2012 or 2011, respectively, had cash-settlement features.

The Company may satisfy the awards upon exercise, or upon fulfillment of the vesting requirements for other equity-based awards, with either authorized but unissued shares or shares reacquired by the Company. Stock-based awards are granted with an exercise price equal to the market price of the Company's stock on the date of grant. Awards contain service or performance conditions and generally become exercisable ratably over one to four years and have a ten year contractual term.

## 6. Earnings Per Share

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

Basic and diluted earnings per share for the three and six months ended June 30, 2012 and 2011 are as follows:

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	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Shares used in the calculation of Basic earnings per share	13,262,023	12,725,216	13,212,424	12,707,143
Effect of dilutive securities:				
Stock options, SARs, RSAs, and shares held in escrow	1,181,771	1,014,620	1,090,015	1,034,194
Diluted shares used in the calculation of earnings per share	14,443,794	13,739,836	14,302,439	13,741,337

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, 2012. These 500,000 shares are included in the diluted potential common shares but are excluded from the basic earnings per share calculation. See Note 10 for additional information relative to this item.

Equity awards of 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. Equity awards of 1,148,154 and 1,088,461 shares were outstanding for the three and six months ended June 30, 2011, respectively, but were not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive.

## 7. Inventories

Inventories consist of the following:

	June 30, 2012	December 31, 2011
Raw materials	\$ 5,502,367	\$ 4,091,366
Work-in-process	1,704,424	1,503,565
Finished goods	3,569,997	1,707,552
Total	\$ 10,776,788	\$ 7,302,483

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead.

## 8. Intangible Assets and Goodwill

In connection with the acquisition of Anika S.r.l., the Company acquired various intangible assets and goodwill. The Company evaluated the various intangibles and related cash flows from these intangible assets, as well as the useful lives and amortization methods related to these intangibles. The in-process research and development intangible assets initially have indefinite lives and are reviewed periodically to assess the project status, valuation, and disposition including write-off(s) for abandoned projects. Until such determination is made, they are not amortized.

The Company reviews its long-lived assets for impairment at least annually. Additionally, the Company will initiate a review for impairment if events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of the assets are no longer appropriate. Each impairment test will be based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value.

Intangible assets as of June 30, 2012 and December 31, 2011 consist of the following:

	June 30, 2012			December 31, 2011		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$ 16,700,000	\$ (1,974,317)	\$ (2,462,946)	\$ 12,262,737	\$ 13,228,351	15
In-process research & development	6,698,000	(820,741 )	-	5,877,259	5,955,066	Indefinite
Distributor relationships	4,700,000	(513,855 )	(2,124,103)	2,062,042	2,547,842	5
Patents	1,000,000	(118,438 )	(141,202 )	740,360	790,555	16
Ele vess trade name	1,000,000	-	(435,924 )	564,076	626,749	9
Total	\$ 30,098,000	\$ (3,427,351)	\$ (5,164,175)	\$ 21,506,474	\$ 23,148,563	

The aggregate amortization expense related to intangible assets was \$506,706 and \$544,776 for the three months ended June 30, 2012 and 2011, respectively. The aggregate amortization expense for the six months ended June 30, 2012 and 2011, was \$1,022,984 and \$1,081,816 respectively.

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

	For the three months ended: June 30, 2012	For the six months ended: June 30, 2012
Balance, beginning	\$ 9,150,273	\$ 8,883,407
Effect of foreign currency adjustments	(522,755 )	(255,889 )
Balance, ending	\$ 8,627,518	\$ 8,627,518

#### 9. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2012	December 31, 2011
Payroll and benefits	\$ 1,988,636	\$ 2,498,492
Professional fees	576,103	1,052,058
Research grants	1,153,418	1,313,280
Other	557,417	457,764
Total	\$ 4,275,574	\$ 5,321,594

#### 10. Commitments and Contingencies

In certain of its contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the product. The Company may also warrant that the products it manufactures do not infringe, violate or breach any patent or intellectual property rights, trade secret or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligence or acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure. Based on the Company's historical activity in combination with its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. The Company has no accrued warranties and has no history of claims paid.

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

are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with Depuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging. We are working with Medtronic to resolve a dispute related thereto. Medtronic has informed us that if we are unable to resolve this dispute, they will make claims against us. As this labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A., we have made claims against Fidia for indemnification for Anika's losses as well as any potential claims that may be brought by Medtronic. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the original transaction. 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.



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, 2012, the Company had an outstanding debt balance of \$10,400,000, at an interest rate of 1.72%. The interest rate payable on our debt is determined, at the Company's option, based on LIBOR plus 1.25%, or the lender's prime rate.

ASC 825, Financial Instruments, requires disclosure about the fair value of financial instruments in interim as well as in annual financial statements. The carrying value of our debt instrument was \$10,400,000 and \$11,200,000 at June 30, 2012 and December 31, 2011, respectively, of which \$1,600,000 was recorded as current at each date. The estimated fair value of our debt, which is a Level 2 instrument for fair value measurement purposes, approximated book value at June 30, 2012 and December 31, 2011, respectively.

#### 12. Income Taxes

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 %. Provisions for income taxes were \$1,349,655 and \$1,541,001 for the three and six-month periods ended June 30, 2011, respectively, based on effective tax rates of 37% for both periods. The increase in the effective tax rates for the periods ended 2012, as compared to the same periods in the previous year, are primarily due to lower tax credits anticipated in the current year, including the federal research & development ("R&D") credit which expired with the 2011 tax year.

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 2008 through 2011 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state purposes. The 2009 through 2011 tax years remain subject to examination by the appropriate governmental authorities in Italy.

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its net operating loss carryforward and its investment tax credit carryforward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that those deferred tax assets are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at June 30, 2012 or December 31, 2011, respectively.

## 13. Related Party

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

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

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

Historically, Anika S.r.l. has relied on Fidia, its former parent company, for several functional activities. In connection with the purchase of Anika S.r.l., the Company has negotiated a lease for approximately 26,000 square feet of office, laboratory and warehouse space in Abano Terme, Italy, and a finished goods supply agreement. We had a net payable to Fidia for past products and services of approximately \$1.3 million at June 30, 2012.

## 14. Segment and Geographic Information

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

Product revenue by product group is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Orthobiologics	\$ 10,903,364	\$ 9,763,597	\$ 21,020,209	\$ 17,799,893
Dermal	155,735	799,605	657,051	1,388,759
Ophthalmic	5,299,732	2,584,820	6,623,726	3,482,629
Surgical	1,464,505	1,566,026	2,448,133	2,679,755
Veterinary	1,058,941	700,633	1,746,486	1,123,804
	\$ 18,882,277	\$ 15,414,681	\$ 32,495,605	\$ 26,474,840

Product revenue by geographic location in total and as a percentage of total product revenue, for the three and six months ended June 30, 2012 and 2011 are as follows:

Geographic Location:	2012		Three Months Ended June 30,		2011	
	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue
United States	\$ 16,011,667	85 %	\$ 11,594,988	75 %		
Europe	1,521,552	8 %	2,604,021	17 %		
Other	1,349,058	7 %	1,215,672	8 %		
Total	\$ 18,882,277	100 %	\$ 15,414,681	100 %		

Geographic Location:	2012		Six Months Ended June 30,		2011	
	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue	Revenue	Percentage of Revenue
United States	\$ 26,401,712	81 %	\$ 19,938,102	75 %		
Europe	3,677,281	11 %	4,637,219	18 %		
Other	2,416,612	8 %	1,899,519	7 %		
Total	\$ 32,495,605	100 %	\$ 26,474,840	100 %		

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

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

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

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

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

The development of possible new products;

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

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

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

Our ability to effectively compete against current and future competitors;

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

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

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

Our and Bausch & Lomb's performance under the non-exclusive supply agreement for AMVISC® and AMVISC® Plus ophthalmic viscoelastic products, and our expectations regarding revenue generated from ophthalmic products;

Our ability to commercialize AnikaVisc and AnikaVisc Plus, and our expectations regarding such commercialization and the potential revenue generated thereby;

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

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

Our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals and commercial launches;

Our expectations regarding revenue from sales of HYVISC®;

Our ability to identify a new distribution partner for HYDRELLE™ in the United States and the impact this may have on future sales of this product;

Our ability to achieve operational efficiencies from the transfer of our manufacturing capabilities to the Bedford facility;

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 development of aesthetics product line extensions;

Our expectations regarding product gross margin;

Our expectations regarding our U.S. MONOVISC® trials and the results of the related premarket approval (“PMA”) filing with the FDA, including the escalation of the appeal process with the FDA and the FDA's review of the additional information requested in order to pass judgment on the appeal, and the likelihood of our obtaining such approval and/or the anticipated timing thereof;

Our expectations regarding the commencement of a clinical trial for Hyalograft C Autograft and CINGAL™, including the expense associated therewith, and our ability to obtain regulatory approvals for these products;

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

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

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

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

Our ability to remain in compliance with debt covenants;

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

Our abilities to successfully manage Anika S.r.l.'s operations from one with losses, into a company generating profits;

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

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

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

Our ability to satisfactorily resolve the potential dispute with Medtronic Xomed and Fidia Farmaceutici S.p.A; 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,” “intend,” “seek,” “designed,” “develop,” “would,” “future,” “can,” “could,” and other expressions that are predictions of or indicate events and trends and which do not relate to historical matters, also identify forward-looking statements.

You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed herein and in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this Quarterly Report on Form 10-Q, as well as the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2011 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors of new information, future events or other changes.

## Management Overview

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

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

Anika S.r.l., our Italian subsidiary, has over 20 products currently commercialized, primarily in Europe. These products are all made from HA, and are based on two technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Both technologies are protected by an extensive portfolio of patents. With the 2009 acquisition of Anika S.r.l., the Company is offering therapeutic products in the following areas:

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

During the first quarter of 2012, the Company entered into an agreement with a new distributor for Anika S.r.l.’s products in the Italian market, which consist of orthopedic and advanced wound care products. The transition to the new distributor resulted in a decline in Italian revenue during the first half of 2012 compared to the prior year. A significant portion of the Company’s accounts receivable arising from product sales within Italy by Anika S.r.l. are due from public hospitals and other government-funded healthcare agencies. As of June 30, 2012, the Company’s accounts receivable from all Italian customers totaled approximately \$2.6 million of which public hospital and agency receivables were approximately \$1.6 million.

Please see Management’s Discussion and Analysis of Financial Condition and Results of Operations-Management Overview (Item 7) to the Company’s Annual Report on Form 10-K for the year ended December 31, 2011, for a description of each of the above therapeutic areas, including the individual products.

## Research and Development

Anika’s research and development efforts primarily consist of the development of new medical applications for our HA-based technologies, the management of clinical trials and studies for certain product candidates, the preparation



and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities relative to our existing and new products. Our development focus includes products for new indications, chemically modified formulations of HA designed for longer residence time in the body, and other development activities. Our investment in R&D has been important over the years, and varies considerably depending on the number and size of clinical trials and studies underway. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

With the acquisition of Anika S.r.l., we have enhanced both our research and development capabilities and our pipeline of candidate products. Anika S.r.l. has research and development programs for new products including Hyalobone, a bone tissue filler; Hyalospine, an adhesion prevention gel for use after spinal surgery; and Hyalograft C Autograft (“HCA”) for cartilage regeneration. The Company currently plans to commence a multi-country, multi-year clinical trial for HCA in September 2012.

Hyalograft C Autograft is classified as an advanced therapy medicinal product under the current European Union regulations, which require a centralized marketing authorization by the European Medicines Agency. Our first next generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary cross-linked HA-technology. We received Conformité Européenne (“CE”) Mark approval for the MONOVISC product in October 2007, and began sales in Europe during the second quarter of 2008, following a small, post-marketing clinical study. In the U.S., we filed the final module of our MONOVISC PMA containing the clinical data in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter, which is the FDA's mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by the FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The FDA denied our request for an Orthopedic Advisory Panel review of the product, and we have now moved to the next level in the appeal process structure of the FDA. On June 12, 2012, the Company attended a supervisory appeal meeting with the Chief Scientific Officer of the Center for Devices and Radiological Health (CDRH), a branch of the FDA, to address concerns related to the non-approvable letter issued by the FDA for the Company's Monovisc PMA. The FDA requested additional information in order to pass judgement on the appeal. The Company has submitted that information, and was promised a timely review and decision by the FDA, although no specific response date was provided. We continue to believe in MONOVISC and the strength of our data, and that MONOVISC should receive FDA approval. Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule to provide broad pain relief for a longer period of time. We filed a CE Mark application in the European Union for CINGAL in November 2011.

#### Contracts

As disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, Anika has been a contract manufacturer for B&L for over 20 years. Anika's Supply Agreement with B&L expired on December 31, 2010. Effective January 1, 2011, we entered into a non-exclusive, two year contract with B&L intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, formerly affiliated low-cost supplier to B&L. Effective January 1, 2012, the parties agreed to a new three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes in 2012, and a lower committed volume for 2013 and 2014. B&L accounted for approximately 16%, or \$9.8 million, of our product revenue for the year ended December 31, 2011, but is expected to be moderately lower in 2012 under the new contract.

#### Litigation and Other Legal Matters

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

are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with Depuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging. We are working with Medtronic to resolve a dispute related thereto. Medtronic has informed us that if we are unable to resolve this dispute, they will make claims against us. As this labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A., we have made claims against Fidia for indemnification for Anika's losses as well as any potential claims that may be brought by Medtronic. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the original transaction. 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.

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

## Results of Operations

Three and Six Months Ended June 30, 2012 Compared to the Three and Six Months Ended June 30, 2011

	Three Months Ended June 30,				Six Months Ended June 30,			
	2012	2011	Inc/(Dec)	Inc/(Dec)	2012	2011	Inc/(Dec)	Inc/(Dec)
Product revenue	\$18,882,277	\$15,414,681	\$3,467,596	22.5 %	\$32,495,605	\$26,474,840	\$6,020,765	22.7 %
Licensing, milestone and contract revenue	742,492	726,171	16,321	2.2 %	1,489,824	1,403,691	86,133	6.1 %
Total revenue	19,624,769	16,140,852	3,483,917	21.6 %	33,985,429	27,878,531	6,106,898	21.9 %
Operating expenses:								
Cost of product revenue	8,084,226	6,655,804	1,428,422	21.5 %	14,497,707	12,260,366	2,237,341	18.2 %
Research & development	1,298,170	1,574,155	(275,985 )	-17.5 %	2,831,273	3,106,820	(275,547 )	-8.9 %
Selling, general & administrative	4,108,503	4,233,316	(124,813 )	-2.9 %	7,459,519	8,277,090	(817,571 )	-9.9 %
Total operating expenses	13,490,899	12,463,275	1,027,624	8.2 %	24,788,499	23,644,276	1,144,223	4.8 %
Income from operations	6,133,870	3,677,577	2,456,293	66.8 %	9,196,930	4,234,255	4,962,675	117.2 %
Interest income (expense), net	(49,129 )	(45,281 )	(3,848 )	8.5 %	(100,332 )	(86,202 )	(14,130 )	16.4 %
Income before income taxes	6,084,741	3,632,296	2,452,445	67.5 %	9,096,598	4,148,053	4,948,545	119.3 %
Provision for income taxes	2,347,873	1,349,655	998,218	74.0 %	3,447,611	1,541,001	1,906,610	123.7 %
Net income	\$3,736,868	\$2,282,641	\$1,454,227	63.7 %	\$5,648,987	\$2,607,052	\$3,041,935	116.7 %
Product gross margin	10,798,051	8,758,877	2,039,174	23.3 %	17,997,898	14,214,474	3,783,424	26.6 %
Product gross margin	57 %	57 %			55 %	54 %		

## Product Revenue

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Product revenue for the quarter ended June 30, 2012 was \$18,882,277, an increase of 22%, as compared to \$15,414,681 for the quarter ended June 30, 2011. Product revenue for the six months ended June 30, 2012 was \$32,495,605, an increase of 23%, as compared to \$26,474,840 for the six months ended June 30, 2011. The second quarter increase was primarily driven by another strong quarter for our orthobiologics franchise, as well as strong performances for the quarter in our ophthalmic and veterinary franchises.

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

	Three Months Ended June 30,		Increase (Decrease)		
	2012	2011	\$		%
Orthobiologics	\$ 10,903,364	\$ 9,763,597	\$ 1,139,767		12 %
Dermal	155,735	799,605	(643,870 )		-81 %
Ophthalmic	5,299,732	2,584,820	2,714,912		105 %
Surgical	1,464,505				