ANIKA THERAPEUTICS INC
Form 10-Q
November 08, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012

o 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	04-3145961
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
32 Wiggins Avenue, Bedford, Massachusetts	01730
(Address of Principal Executive Offices)	(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 x No o

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 x No o

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

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

As of November 1, 2012 there were 13,812,747 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)

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$39,855,856	$35,777,222
Accounts receivable, net of reserves of $464,442 and $334,473 at September 30, 2012 and December 31, 2011, respectively	16,343,600	17,307,786
Inventories	8,932,492	7,302,483
Current portion deferred income taxes	1,918,926	1,918,926
Prepaid expenses and other	1,351,403	1,831,127
Total current assets	68,402,277	64,137,544
Property and equipment, at cost	52,141,685	50,850,630
Less: accumulated depreciation	(16,204,216)	(14,380,752)
	35,937,469	36,469,878
Long-term deposits and other	249,381	205,042
Intangible assets, net	21,464,089	23,148,563
Goodwill	8,818,920	8,883,407
Total Assets	$134,872,136	$132,844,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,907,564	$4,299,680
Accrued expenses	4,389,002	5,321,594
Deferred revenue	2,866,667	2,866,667
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	1,391,694	450,482
Total current liabilities	12,154,927	14,538,423
Other long-term liabilities	1,539,198	1,548,652
Long-term deferred revenue	2,869,440	5,019,440
Deferred tax liability	6,435,148	7,375,141
Long-term debt	8,400,000	9,600,000
Commitments and contingencies (Note 10)	-	-
Stockholders' equity:		
Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	-	-
Common stock, $.01 par value; 30,000,000 shares authorized, 13,804,975 and 13,630,607 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	138,049	136,305
Additional paid-in-capital	65,142,128	63,441,433
Accumulated currency translation adjustment	(3,353,212)	(3,067,181)
Retained earnings	41,546,458	34,252,221
Total stockholders' equity	103,473,423	94,762,778
Total Liabilities and Stockholders' Equity	$134,872,136	$132,844,434

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Product revenue	$14,055,440	$17,756,000	$46,551,045	$44,230,840
Licensing, milestone and contract revenue	711,171	699,817	2,200,995	2,103,508
Total revenue	14,766,611	18,455,817	48,752,040	46,334,348
Operating expenses:				
Cost of product revenue	7,221,028	7,394,922	21,718,735	19,655,288
Research & development	1,217,086	1,531,355	4,048,359	4,638,175
Selling, general & administrative	3,601,737	4,712,178	11,061,256	12,989,268
Total operating expenses	12,039,851	13,638,455	36,828,350	37,282,731
Income from operations	2,726,760	4,817,362	11,923,690	9,051,617
Interest income (expense), net	(45,161)	(46,269)	(145,493)	(132,471)
Income before income taxes	2,681,599	4,771,093	11,778,197	8,919,146
Provision for income taxes	1,036,349	1,794,575	4,483,960	3,335,576
Net income	$1,645,250	$2,976,518	$7,294,237	$5,583,570
Basic net income per share:				
Net income	$0.12	$0.23	$0.55	$0.44
Basic weighted average common shares outstanding	13,287,463	12,817,910	13,237,629	12,744,471
Diluted net income per share:				
Net income	$0.11	$0.22	$0.51	$0.41
Diluted weighted average common shares outstanding	14,459,154	13,765,533	14,357,791	13,729,835
Net income	$1,645,250	$2,976,518	$7,294,237	$5,583,570
Other comprehensive income				
Foreign currency translation adjustment	557,712	(1,576,131)	(286,031)	768,731
Comprehensive income	$2,202,962	$1,400,387	$7,008,206	$6,352,301

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

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

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income	$7,294,237	$5,583,570
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,364,432	2,943,295
Stock-based compensation expense	914,003	901,619
Deferred income taxes	(1,012,571)	1,116,456
Provision for doubtful accounts	135,353	-
Provision for inventory	790,379	642,120
Tax benefit from exercise of stock options	(456,796)	-
Changes in operating assets and liabilities:		
Accounts receivable	716,874	(2,721,155)
Inventories	(2,433,367)	516,647
Prepaid expenses, other current and long-term assets	429,718	454,804
Long-term deposits and other	25,496	162,997
Accounts payable	(2,399,999)	(6,252,826)
Accrued expenses	(873,153)	51,152
Deferred revenue	(2,150,000)	(1,884,307)
Income taxes payable	1,398,008	1,368,665
Other long-term liabilities	(6,318)	(17,224)
Net cash provided by operating activities	5,736,296	2,865,813
Cash flows from investing activities:		
Purchase of property and equipment	(1,292,487)	(953,952)
Net cash used in investing activities	(1,292,487)	(953,952)
Cash flows from financing activities:		
Principal payments on debt	(1,200,000)	(1,200,000)
Proceeds from exercise of stock options	331,639	151,770
Tax benefit from exercise of stock options	456,796	-
Net cash used in financing activities	(411,565)	(1,048,230)
Exchange rate impact on cash	46,390	(16,899)
Increase in cash and cash equivalents	4,078,634	846,732
Cash and cash equivalents at beginning of period	35,777,222	28,201,932
Cash and cash equivalents at end of period	$39,855,856	$29,048,664

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

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

1. Nature of Business

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

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

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in accordance with accounting principles generally accepted in the United States ("U.S."). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. The year-end consolidated balance sheet is derived from our audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of September 30, 2012 and the results of its operations for the three and nine months ended September 30, 2012 and 2011 and cash flows for the nine months ended September 30, 2012 and 2011.

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

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

3. Recent Accounting Pronouncements Issued or Adopted

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

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

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

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

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

4. Fair Value Measurements

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

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

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

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

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

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

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

5. Equity Incentive Plan

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

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

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

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

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

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

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

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

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

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

6. Earnings Per Share

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

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

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

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

Equity awards of 133,064 and 104,187 shares were outstanding for the three and nine months ended September 30, 2012, respectively, but were not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive. Equity awards of 1,674,331 and 1,057,096 shares were outstanding for the three and nine months ended September 30, 2011, respectively, but were not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive.

7. Inventories

Inventories consist of the following:

	September 30, 2012	December 31, 2011
Raw materials	$5,655,726	$4,091,366
Work-in-process	1,450,843	1,503,565
Finished goods	1,825,923	1,707,552
Total	$8,932,492	$7,302,483

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

8. Intangible Assets and Goodwill

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

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

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

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

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

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

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

9. Accrued Expenses

Accrued expenses consist of the following:

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

10. Commitments and Contingencies

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

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

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

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