ANIKA THERAPEUTICS INC
Form 10-Q
November 06, 2008

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, 2008

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 (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 last 90 days. 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 definitions of accelerated filer and large accelerated filer in Rule 12b-2 of the Securities Exchange Act. (Check One):

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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

At November 3, 2008, there were 11,382,473 outstanding shares of Common Stock, par value $.01 per share.

PART I: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiary

Consolidated Balance Sheets

(unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,368,244	$ 35,903,569
Short-term investments		3,501,974
Accounts receivable, net of reserves of $60,000	6,529,709	5,795,973
Inventories	5,040,565	4,390,118
Current portion deferred income taxes	1,657,007	1,657,007
Prepaid expenses and other	332,283	1,194,081
Total current assets	48,927,808	52,442,722
Property and equipment, at cost	41,179,203	28,101,422
Less: accumulated depreciation	(9,852,157)	(8,731,706)
	31,327,046	19,369,716
Long-term deposits and other	561,334	433,081
Intangible asset, net	950,981	995,098
Deferred income taxes	6,524,229	6,256,067
Total Assets	$ 88,291,398	$ 79,496,684
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,736,450	$ 4,866,619
Accrued expenses	2,768,668	2,760,010
Deferred revenue	2,813,024	2,806,778
Current portion of long-term debt	600,000	
Income taxes payable	494,067	203,954
Total current liabilities	9,412,209	10,637,361
Other long-term liabilities	729,271	398,365
Long-term deferred revenue	11,475,001	13,500,001
Long-term debt	7,400,000	
Commitments and contingencies (Note 8)		
Stockholders equity		
Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding		
Common stock, $.01 par value; 30,000,000 shares authorized, 11,353,473 shares issued and outstanding at September 30, 2008, 11,223,273 shares issued and outstanding at December 31, 2007	113,535	112,233
Additional paid-in-capital	42,473,908	40,695,940
Retained earnings	16,687,474	14,152,784
Total stockholders equity	59,274,917	54,960,957
Total Liabilities and Stockholders Equity	$ 88,291,398	$ 79,496,684

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

Anika Therapeutics, Inc. and Subsidiary

Consolidated Statements of Operations

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Product revenue	$ 8,523,765	$ 7,283,129	$ 24,770,230	$ 18,989,133
Licensing, milestone and contract revenue	681,250	682,251	2,043,753	2,213,855
Total revenue	9,205,015	7,965,380	26,813,983	21,202,988
Operating expenses:				
Cost of product revenue	3,504,986	3,138,307	10,365,586	8,655,010
Research & development	1,801,561	1,125,826	4,954,520	2,969,218
Selling, general & administrative	2,567,000	1,820,998	8,515,772	5,112,147
Total operating expenses	7,873,547	6,085,131	23,835,878	16,736,375
Income from operations	1,331,468	1,880,249	2,978,105	4,466,613
Interest income, net	130,486	550,014	477,767	1,692,622
Income before income taxes	1,461,954	2,430,263	3,455,872	6,159,235
Provision for income taxes	357,751	634,033	921,182	1,797,377
Net income	$ 1,104,203	$ 1,796,230	$ 2,534,690	$ 4,361,858
Basic net income per share:				
Net income	$ 0.10	$ 0.16	$ 0.22	$ 0.40
Basic weighted average common shares outstanding	11,329,422	11,152,686	11,294,928	11,018,208
Diluted net income per share:				
Net income	$ 0.10	$ 0.16	$ 0.22	$ 0.38
Diluted weighted average common shares outstanding	11,485,989	11,568,074	11,479,797	11,438,673

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

Anika Therapeutics, Inc. and Subsidiary

Consolidated Statements of Cash Flows

For the Nine Months Ended

(unaudited)

	September 30, 2008	September 30, 2007
Cash flows from operating activities:		
Net income	$ 2,534,690	$ 4,361,858
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,080,320	519,064
Amortization of premium on short-term investment	1,974	17,993
Stock-based compensation expense	1,072,538	638,756
Deferred income taxes	(268,162)	(228,377)
Provision for inventory reserve	26,172	91,579
Tax benefit from exercise of stock options	(229,920)	(399,197)
Changes in operating assets and liabilities:		
Accounts receivable	(733,736)	(1,456,438)
Inventories	(676,620)	591,386
Prepaid expenses, other current and long-term assets	821,267	(446,765)
Accounts payable and accrued expenses	(172,617)	549,231
Deferred revenue	(2,018,754)	1,410,006
Income taxes payable	520,033	765,280
Other long-term liabilities	262,906	203,718
Net cash provided by operating activities	2,220,091	6,618,094
Cash flows from investing activities:		
Proceeds from maturity of short-term investment	3,500,000	
Purchase of short-term investment		(3,526,985)
Purchase of property and equipment, net	(14,874,426)	(6,233,185)
Net cash used in investing activities	(11,374,426)	(9,760,170)
Cash flows from financing activities:		
Proceeds from long-term debt	8,000,000	
Debt issuance costs	(87,721)	
Proceeds from exercise of stock options	476,811	1,645,261
Tax benefit from exercise of stock options	229,920	489,021
Net cash provided by financing activities	8,619,010	2,134,282
Decrease in cash and cash equivalents	(535,325)	(1,007,794)
Cash and cash equivalents at beginning of year	35,903,569	47,167,432
Cash and cash equivalents at end of year	$ 35,368,244	$ 46,159,638
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 10,000	$ 1,164,000

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

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

1. Nature of Business

Anika Therapeutics, Inc. (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 s currently manufactured and marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans; AMVISC®, AMVISC® Plus, STAARVISC -II, and ShellGel™, each an injectable ophthalmic viscoelastic HA product; ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation; HYVISC®, which is an HA product used in the treatment of equine osteoarthritis; and INCERT®, which is an HA based anti-adhesive for surgical applications. In the U.S., ORTHOVISC® is marketed by DePuy Mitek, Inc. (Depuy Mitek), a subsidiary of Johnson & Johnson, under the terms of a licensing, distribution, supply and marketing agreement. Outside the U.S., ORTHOVISC® has been approved for sale since 1996 and is marketed by distributors in approximately 17 countries. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints, is available in Europe. MONOVISC , a single-injection osteoarthritis product based on our proprietary cross-linking technology, is also available in Europe. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. ELEVESS is marketed in the U.S. by Artes Medical, Inc. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. INCERT® is currently marketed in three countries outside of the U.S. Products in development include next generation joint health related products and ELEVESS line extensions.

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) regulations and approval requirements as well as the ability to grow the Company s business.

2. Basis of Presentation

The accompanying consolidated financial statements have been prepared by the Company without audit, 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. In the opinion of management, these consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the financial position of the Company as of September 30, 2008 and the results of its operations for the three and nine months ended September 30, 2008 and 2007 and its cash flows for the nine months ended September 30, 2008 and 2007.

The accompanying 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, 2007. The results of operations for the three and nine

months ended September 30, 2008 are not necessarily indicative of the results to be expected for the year ending December 31, 2008 or any future periods.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiary, Anika Securities, Inc. (a Massachusetts Securities Corporation). All intercompany balances and transactions have been eliminated in consolidation.

Cash, Cash Equivalents and Short-term Investments

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of 90 days or less. The Company accounts for short-term investments in accordance with the Statement of Financial Accounting Standards (SFAS) No. 115, Accounting for Certain Investments in Debt and Equity Securities . The Company determines the appropriate classification of all short-term investments as held-to-maturity, available-for-sale or trading at the time of purchase and re-evaluates such classifications as of each balance sheet date. At September 30, 2008 and December 31, 2007, cash equivalents consisted of funds invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations. At December 31, 2007, the Company also had a short-term municipal bond that was carried on our books at amortized cost, which approximated fair market value.

Revenue Recognition

The Company s revenue recognition policies are in accordance with the SEC Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, as amended by SEC Staff Accounting Bulletin No. 104, Revenue Recognition, and Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables.

Product Revenue

The Company recognizes revenue from the sales of products it manufactures upon confirmation of regulatory compliance and shipment to the customer as long as there is (1) persuasive evidence of an arrangement, (2) delivery has occurred and risk of loss has passed, (3) the sales price is fixed or determinable and (4) collection of the related receivable is reasonably assured. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. When determining whether risk of loss has transferred to customers on product sales or if the sales price is fixed or determinable, the Company evaluates both the contractual terms and conditions of its distribution and supply agreements as well as its business practices. Product revenue also includes royalties. Royalty revenue is based on our distributor s sales and recognized in the same period that our distributor records their sale of the product.

License, Milestone and Contract Revenue

License, milestone and contract revenue consists of revenue recognized on initial and milestone payments as well as other contractual amounts received from partners. The Company s business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company s products. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on product sales. The Company evaluates each agreement and elements within each agreement in accordance with EITF 00-21. Under EITF 00-21, in order to account for an element as a separate unit of accounting, the element must have stand-alone value and there must be objective and reliable evidence of fair value of the undelivered elements. In general, non-refundable upfront fees and milestone payments are recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company s best estimate of the amount of probable credit losses in its existing accounts receivable. The Company determines the allowance based on specific identification. The Company reviews its allowance for doubtful accounts at least quarterly. Past due balances over 90 days are reviewed individually for collectibility. Account balances are charged-off against the allowance when the Company feels it is probable the receivable will not be recovered.

Fair Value Measurements

On January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements (SFAS No. 157), for our financial assets and liabilities. Our adoption of SFAS No. 157 did not impact our financial position, results of operations or liquidity. In accordance with FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157 (FSP FAS 157-2), we elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is currently evaluating the potential impact of adopting FSP FAS 157-2.

On January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements (SFAS No. 157), for our financial ass

SFAS No. 157 establishes a three-level hierarchy which prioritizes the inputs used in measuring fair value. In general, fair value determined by Level 1 inputs utilize quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability. The fair value, Level 1, of our cash equivalents was $34,175,393 at September 30, 2008.

Property and equipment

Property and equipment are carried at cost less accumulated depreciation, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Costs of major additions and improvements are capitalized; maintenance and repairs that do not improve or extend the life of the respective assets are charged to operations. On disposal, the related accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in results of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful life or the expected term of the respective lease. Machinery and equipment are depreciated from 5 to 10 years, furniture and fixtures for 5 to 7 years and computer software and hardware from 3 to 5 years. Interest costs incurred during the construction of major capital projects are capitalized in accordance with Statement of Financial Accounting Standards No. 34, Capitalization of Interest Costs , (SFAS No. 34). The interest is capitalized until the underlying asset is ready for its intended use, at which point the interest cost is amortized as interest expense over the life of the underlying assets. We capitalize certain direct and incremental costs associated with the validation effort related to FDA approval of our manufacturing facility and equipment for the production of our commercial products. These costs include construction costs, equipment costs, direct labor and materials incurred in preparing the facility and equipment for their intended use. The validation costs are amortized over the life of the related facility and equipment.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, (SFAS 123R), Share-Based Payment, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS No. 123R, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employee s requisite service period (generally the vesting period of the equity grant). For awards with a performance condition vesting feature, when achievement of the performance condition is deemed probable, the Company recognizes compensation cost on a graded-vesting basis over the awards expected vesting periods. The Company assesses probability on a quarterly basis. Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with Accounting Principles Board Opinion No. 25, (APB 25) Accounting for Stock Issued to Employees, and related interpretations. The Company also followed the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure. See Note 5 for additional disclosures.

Disclosures About Segments of an Enterprise and Related Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding how to allocate resources and assess performance. The Company s chief operating decision maker is its Chief Executive Officer. Based on the criteria established by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, the Company has one reportable operating segment, the results of which are disclosed in the accompanying consolidated financial statements. All of the operations and assets of the Company have been derived from and are located in the United States.

Product revenue by product group is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Ophthalmic	$ 2,703,095	$ 2,893,906	$ 8,283,984	$ 8,068,611
Joint Health	4,676,247	3,596,395	13,563,901	8,894,752
Veterinary	706,553	552,773	2,427,570	1,682,870
Aesthetics	383,320	222,220	399,370	224,220
Other	54,550	17,835	95,405	118,680
	$ 8,523,765	$ 7,283,129	$ 24,770,230	$ 18,989,133

Product revenue by significant customers as a percent of product revenue is as follows:

	Percent of Product Revenue Three Months Ended September 30,		Percent of Product Revenue Nine Months Ended September 30,	
	2008	2007	2008	2007
Depuy Mitek	36.5%	34.3%	38.7%	35.7%
Bausch & Lomb Incorporated	29.8%	36.5%	31.1%	38.6%
Boehringer Ingelheim Vetmedica	8.3%	7.6%	9.8%	8.9%
Biomeks	6.4%	7.0%	4.9%	3.9%
	81.0%	85.4%	84.5%	87.1%

As of September 30, 2008, seven customers represented 94% of the Company s accounts receivable balance and as of December 31, 2007, five customers represented 93% of the Company s accounts receivable balance.

Product revenue by geographic location in total and as a percentage of total product revenue, for the three and nine months ended September 30, 2008 and 2007, are as follows:

	Three Months Ended September 30,			
	2008		2007	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:				
United States	$ 6,062,837	71.1%	$ 5,057,754	69.4%
Europe	1,515,983	17.8%	1,213,728	16.7%
Other	944,945	11.1%	1,011,647	13.9%
Total	$ 8,523,765	100.0%	$ 7,283,129	100.0%

	Nine Months Ended September 30,			
	2008		2007	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:				
United States	$ 18,180,180	73.4%	$ 14,176,658	74.6%
Europe	4,087,182	16.5%	3,221,686	17.0%
Other	2,502,868	10.1%	1,590,789	8.4%
Total	$ 24,770,230	100.0%	$ 18,989,133	100.0%

Income Taxes

Beginning January 1, 2007, the Company began accounting for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement in accordance with FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (FIN 48). If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit will be recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. As a result of the adoption of FIN 48, there was no change to the tax reserve for unrecognized tax benefits. As such, there was no change to retained earnings as of January 1, 2007. It is the Company s policy to classify accrued interest and penalties as part of the accrued FIN 48 liability and record the expense in the provision for income taxes.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates assumed to be in effect when these differences reverse. As of September 30, 2008, management determined that it is more likely than not that the deferred tax assets will be realized and, therefore, a valuation allowance has not been recorded.

Recent Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board (FASB) issued Financial Accounting Standards Board Staff Position (FSP) Emerging Issues Task Force (EITF) Issue 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities . FSP EITF 03-6-1 clarifies that share-based payment awards that entitle their holders to receive nonforfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments should be included in the calculation of basic earnings per share. FSP EITF 03-6-1 is effective for the Company in 2009. The Company does not expect a material effect from the adoption of this standard.

In May 2008, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS No. 162). This Standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the U.S. The Company is evaluating the impact of this standard on its financial statements.

In April 2008, the FASB issued FSP No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets . The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS

No. 141(R), Business Combinations, and other U.S. generally accepted accounting principles. This FSP is effective for the Company on January 1, 2009 and early adoption is prohibited. The Company is evaluating the impact of this standard on its financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities (SFAS No. 161), an amendment of FASB Statement No. 133 (SFAS No. 133). SFAS No. 161 requires enhanced disclosures regarding an entity s derivative and hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, and its related interpretations; and how derivative instruments and related hedge items affect an entity s financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued

for fiscal years and interim periods beginning after November 15, 2008. SFAS No. 161 will not have an impact on the Company s financial position, results of operations or liquidity as the Company does not have or expect to have derivative instruments or to engage in hedging activities.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 (EITF 07-1), Accounting for Collaborative Arrangements . EITF 07-1 is effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9. The Company is assessing the impact of adoption of EITF 07-1 on its financial position and results of operations.

4. Short-term Investment

In February 2007, the Company purchased a tax exempt municipal bond for a cost of $3,526,985 with a par value of $3,500,000 and an interest rate of 4.25%. This investment matured on February 1, 2008. The Company classifies its investments in debt and equity securities into held-to-maturity, available-for-sale or trading categories in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 115, Accounting For Certain Investments in Debt and Equity Securities . The tax exempt municipal bond was classified as held-to-maturity in 2007 because the Company intended, and held the security to maturity. Held-to-maturity securities are stated at amortized cost.

5. Stock-Based Compensation

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 and stock appreciation rights award during the three and nine months ended September 30, 2008 and 2007 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	September 30, 2008	**September 30, 2007**
Risk-free interest rate	2.39% - 2.82%	4.12%
Expected volatility	58.15% - 63.37%	56.67%
Expected lives (years)	3 - 4	4
Expected dividend yield	0.00%	0.00%

	Nine Months Ended	
	September 30, 2008	**September 30, 2007**
Risk-free interest rate	2.39% - 2.82%	4.12% - 4.80%
Expected volatility	58.15% - 63.37%	56.67% - 64.11%
Expected lives (years)	3 - 4	4

Expected dividend yield	0.00%	0.00%

The Company recorded $368,105 and $1,072,538 of share-based compensation expense for the three and nine months ended September 30, 2008, respectively, for stock options, stock appreciation rights and restricted stock awards. The Company recorded $151,877 and $638,756 of share-based compensation expense for the three and nine months ended September 30, 2007, respectively, for stock options, stock appreciation rights and restricted stock awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the same employees.

Stock Option Plans

The Company had reserved 3,485,000 shares of common stock for the grant of stock options to employees, directors, consultants and advisors under the Anika Therapeutics, Inc. 1993 Stock Option Plan, as amended (the 1993 Plan). In addition, the Company also established the Directors Stock Option Plan (the Directors Plan) and reserved 40,000 shares of the Company s common stock for issuance to the Board of Directors. On March 3, 2003, the 1993 Plan expired in accordance with its terms and approximately 662,000 shares reserved under the 1993 plan were released. On April 4, 2003 the Board of Directors approved the 2003 Anika Therapeutics, Inc. Stock Option and Incentive Plan (the 2003 Plan). The Company has reserved 1,500,000 shares of common stock for grant to employees, directors, consultants and advisors under the 2003 Plan, which was approved by stockholders on June 4, 2003. The Company issues new shares upon share option exercise from its authorized shares. Stock-based awards are granted with an exercise price equal to the market price of the Company s stock on the date of grant. The Company s stock-based awards contain service or performance conditions. Awards generally vest over 3 to 4 years with an equal percent of the shares vesting on each of the four anniversary dates from the grant date. Awards have 10-year contractual terms.

6. Earnings Per Share

The Company reports earnings per share in accordance with SFAS No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income 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.

Shares used in calculating basic and diluted earnings per share for the three and nine months ended September 30, 2008 and 2007, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Basic weighted average common shares outstanding	11,329,422	11,152,686	11,294,928	11,018,208
Dilutive potential common shares	156,567	415,388	184,869	420,465
Diluted weighted average common and potential common shares outstanding	11,485,989	11,568,074	11,479,797	11,438,673

Equity awards of 903,208 and 677,402 shares were outstanding at the three and nine months ended September 30, 2008, respectively, but not included in the computation of diluted earnings per share because the awards exercise prices were greater than the average market price during the period. Equity awards of 10,000 and 110,000 shares were outstanding at the three and nine months ended September 30, 2007, respectively, but not included in the computation of diluted earnings per share because the awards exercise prices were greater than the average market price during the period.

7. Inventories

Inventories consist of the following:

	September 30, 2008	December 31, 2007
Raw materials	$ 3,184,251	$ 2,689,358
Work-in-process	1,468,775	1,541,968
Finished goods	387,539	158,792
Total	$ 5,040,565	$ 4,390,118

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

8. Guarantor Arrangements

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.

9. Long-term Debt

On January 31, 2008, the Company entered into an unsecured Credit Agreement (the Agreement) with Bank of America. Bank of America has agreed to provide the Company with an unsecured revolving credit facility through December 31, 2008 of up to a maximum principal amount at any time outstanding of $16,000,000. On December 31, 2008, all outstanding revolving credit loans will convert into a term loan with quarterly principal payments and a maturity date of December 31, 2015. Interest on revolving credit loans and term loans will be payable at a rate based upon (at the Company s election) either Bank of America s prime rate or LIBOR plus 75 basis points. The Agreement contains customary representations and warranties of the Company, affirmative and negative covenants regarding the Company s operations, financial covenants regarding the maintenance by the Company of a specified quick ratio and consolidated fixed charge coverage ratio, and events of default. As of September 30, 2008, the Company had an outstanding debt balance of $8,000,000, at a blended interest rate of 3.72%. The Company recorded approximately $171,000 as deferred issuance costs, which is being amortized over the life of the long-term debt. During the nine months ended September 30, 2008, the Company capitalized interest expense of $157,578 as part of construction in progress related to the Company s new facility build-out. Interest capitalization was recorded in accordance with SFAS No. 34, Capitalization of Interest Costs.

10. Income Taxes

Income tax expense was $357,751 and $634,033 for the three months ended September 30, 2008 and 2007, respectively. Income tax expense was $921,182 and $1,797,377 for the nine months ended September 30, 2008 and 2007, respectively. The effective tax rates were 24.5% and 26.1% for the three months ended September 30, 2008 and 2007, respectively. The effective tax rates were 26.7% and 29.2% for the nine months ended September 30, 2008 and 2007, respectively. The decrease in effective tax rate was primarily due to an increase in a Massachusetts investment tax credit as a result of expenditures related to the Company s facility project. On October 3, 2008 the Senate passed a financial bailout bill which included the extension of Federal research tax credit to December 31, 2009. This extension will have a favorable impact on the Company s full year effective tax rate beginning in the quarter ending December 31, 2008.

During the third quarter of 2008, the Company concluded its audit by the Massachusetts Department of Revenue (DoR) for its 2004 and 2005 tax returns, which resulted in a reduction to its FIN 48 tax reserves and a related income tax benefit of approximately $100,000. Also during the third quarter, the Company recorded additional provision of $93,000 related to the reduction of its deferred tax assets as a result of newly

enacted changes to the State of Massachusetts to gradually reduce future corporate income tax rates. The impact of these two events on the Company s tax provision was approximately equal and offsetting. Our U.S. federal income tax returns for the years 2005, 2006, and 2007 remain subject to examination, and our state income tax returns for the years 2006 and 2007 remain subject to examination.

11. Trademark Opposition

On December 12, 2007, Colbar Lifescience Ltd., a subsidiary of Johnson and Johnson, filed an opposition proceeding before the U.S. Patent & Trademark Office s Trademark Trial & Appeal Board (Trademark Board), objecting to one of the Company s applications to register the trademark ELEVESS, alleging that the mark is confusingly similar to Colbar s previously registered mark EVOLENCE. The only potential relief available in this proceeding is the denial of the Company s trademark application; no damages or injunctive relief are possible. In October 2008, Colbar filed a petition with the Trademark Board requesting cancellation of the Company s second ELEVESS trademark that had been registered in September 2008. The Company believes Colbar s claim and recent petition are without merit, and has denied all substantive allegations in the notice of opposition, and the parties are exploring settlement possibilities. As of September 30, 2008, the carrying value of the intangible asset related to ELEVESS was $950,981 and the Company does not believe any impairment of the asset has occurred.

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 revenues, 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;

- development of possible new products;

- our ability to achieve or maintain compliance with laws and regulations;

- the timing of and/or receipt of FDA, foreign or other regulatory approvals and/or reimbursement approvals of current, new or potential products, and any limitations on such approvals;

- 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;