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;

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

- our and Bausch & Lomb s performance under the existing supply agreement for certain of our ophthalmic viscoelastic products, our ability to remain the exclusive global supplier for AMVISC and AMVISC Plus to Bausch & Lomb, and our expectations regarding revenue from ophthalmic products;

- our expectations regarding our joint health products, including expectations regarding new products, expanded uses of existing projects, and new distribution;

- 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 sales to DePuy Mitek and the positive effects on domestic ORTHOVISC sales related to DePuy Mitek s sales efforts;

- our expectations regarding HYVISC sales;

- our expectations regarding ELEVESS sales;

- our expectations regarding the development and commercialization of INCERT, and the market potential for INCERT;

- our expectations regarding product gross margin;

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

- our expectations regarding the commencement of our clinical trial for CINGAL;

- our expectation for increases 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 increases in capital expenditures and decline in interest income;

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

- our expectations regarding our existing manufacturing facility and the new Bedford, MA facility, our expectations related to costs, including financing costs, to build-out and occupy the new facility, the timing of construction, and our ability to obtain FDA licensure for the facility;

- our abilities to comply with debt covenants;

- our plans to address the FDA s Warning Letter and Form 483 Notice of Observations; and

- our abilities to successfully defend our ELEVESS trademark.

Furthermore, additional statements identified by words such as will, likely, may, believe, expect, anticipate, intend, seek, designed, develop, would, future, can, could, outlook and other expressions that are predictions of or indicate future 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. 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 Discussions 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, 2007 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to 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. (Anika, the Company, we, us, or our) was incorporated in 1992 as a Massachusetts company and commenced busi as an independent company in 1993. Anika develops, manufactures and commercializes therapeutic products for tissue protection, healing and repair. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells. Our 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®, an HA product used in the treatment of equine osteoarthritis; and INCERT®, 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 (collectively, JNJ), 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 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.

Osteoarthritis Business

Our joint health products include ORTHOVISC, ORTHOVISC *mini*, and MONOVISC. ORTHOVISC is available in the U.S., Canada, and some international markets for the treatment of osteoarthritis of the knee, and in Europe for the treatment of osteoarthritis in all joints. ORTHOVISC® *mini* is available in Europe and is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment for all joints, and is available in Europe and Turkey. ORTHOVISC *mini*, and MONOVISC are our two newest OA products and became available during the second quarter of 2008. Our revenue from joint health products has increased 52.5% through the first nine months of 2008. This increase in many countries is reflective of our continued focus in this therapeutic area, an area with favorable demographics of an aging population looking to remain active. Our strategy is to continue to add new products, to expand the indications for usage of the products, and to add additional countries to our distribution network. The joint health area has been the fastest growing area for the Company, growing from 39% of our product revenue in 2005 to 55% of our revenue for the first nine months of this year. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2008 compared to 2007.

Sales of HYVISC, our veterinary product for the treatment of equine osteoarthritis, contributed 8.3% and 9.8% of our product revenue for the three and nine months ended September 30, 2008, and increased 27.8% and 44.3% compared to the three and nine month periods of 2007. The increases for both periods were a combination of the increased sales people and resources by our partner, Boehringer Ingelheim Vetmedica, to maintain its leading market share position, as well as its order patterns. We expect HYVISC sales to increase in 2008 compared to 2007.

Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the three and nine months ended September 30, 2008, sales of ophthalmic products contributed 31.7% and 33.4% of our product revenue. Ophthalmic sales decreased by 6.6% and increased by 2.7% for the three and nine months periods in 2008 compared to the same periods in 2007. The decrease in sales for the three month period and increase in sales for the nine month period were primarily due to order timing and inventory planning by our partners. Sales to Bausch & Lomb accounted for 94.0% and 93.0% of ophthalmic sales for the three and nine months ended September 30, 2008, and contributed 29.8% and 31.1% of product revenue for the same periods, respectively. For 2008, we only expect a slight increase in ophthalmic revenue compared to 2007.

Aesthetic Dermatology Business

ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA. We received European, Canadian, and United States FDA approvals for our initial commercial product in 2007. In July 2008, we entered into a distributor agreement with Artes Medical, Inc. for distribution of ELEVESS in the U.S. Shipments of commercial product and sample units commenced shortly after the signing of the distribution agreement, with product launch initiated in early August 2008. In October 2008, we entered into an exclusive agreement with Canderm Pharma, Inc., Canada s leading independent skincare company, to distribute and market ELEVESS throughout Canada. We expect shipments of commercial product and sample units to grow in the fourth quarter of 2008 and in 2009. We continue to seek international marketing and distribution partners to commercialize ELEVESS in key markets outside the United States.

Anti-adhesion Business

INCERT, approved for sale in Europe and Turkey, is designed as a family of HA based product, with chemically modified, cross-linked HA, for prevention of post-surgical adhesions. We commenced INCERT sales during the second quarter of 2006. INCERT is currently marketed in three countries. We see potential for expanded indications for the use of INCERT, but have made this a secondary goal to the successful launch and expanded distribution of our joint health and aesthetic products. There are currently no plans at this time to distribute INCERT in the U.S.

Research and Development

Products in development include next generation osteoarthritis/joint health products and line extensions for ELEVESS. Our next generation osteoarthritis products include a single-injection treatment product that uses a non-animal source HA, and is our first osteoarthritis product based on our proprietary crosslinked HA- technology. This product has been branded as MONOVISC. We received *Conformité Européene* (CE) Mark approval for the MONOVISC product in October 2007. We launched MONOVISC in Europe during the second quarter of 2008, following a limited clinical study. In the U.S., we filed an investigational device exemption, or an IDE application, with the FDA, and commenced patient enrollment for our U.S. clinical trial in January of 2008. We currently expect patient enrollment for our U.S. clinical trial to be completed by the end of 2008. Our second single-injection osteoarthritis

product is CINGAL , which is based on the same technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time. We expect to commence a clinical trial for CINGAL in 2009.

FDA Warning Letter

In July 2008, we received a Warning Letter (the Warning Letter) from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our Woburn facility. We have fully cooperated with the FDA to address the issues in the Form 483 filing and have issued a response to the FDA s Warning Letter. We have developed a corrective action plan and we will provide the FDA with progress reports as promised. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. We expect the FDA will conduct an unannounced inspection in the near future. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter by early 2009. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems and investing to make those systems best-in-class. Failure to comply with applicable regulatory requirements and to address the issues raised by the FDA in the Warning Letter could result in regulatory action. Any such regulatory action would be expected to have a material adverse effect on our business and operations.

Summary of Critical Accounting Policies; Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We monitor our estimates on an on-going basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management s Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 3 to the Consolidated Financial Statements of this Quarterly Report on Form 10-Q for the three and nine month periods ended September 30, 2008 and our Annual Report on Form 10-K for the year ended December 31, 2007.

Revenue Recognition

The Company s revenue recognition policies are in accordance with the Securities and Exchange Commission s (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.

Reserve for Obsolete/Excess Inventory

Inventories are stated at the lower of cost or market. We regularly review our inventories and record a provision for excess and obsolete inventory based on certain factors that may impact the realizable value of our inventory including, but not limited to, technological changes, market demand, inventory cycle time, regulatory requirements and significant changes in our cost structure. If ultimate usage varies significantly from expected usage or other factors arise that are significantly different than those anticipated by management, additional inventory write-down or increases in obsolescence reserves may be required.

We generally produce finished goods based upon specific orders or in anticipation of specific orders. As a result, we generally do not establish reserves against finished goods. We evaluate the value of inventory on a quarterly basis and may, based on future changes in facts and circumstances, determine that a write-down of inventory is required in future periods.

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 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

16

grant).

The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, the expected option term, the expected volatility of the Company s stock over the option s expected term, the risk-free interest rate over the option s expected term, and the Company s expected annual dividend yield. The Company uses historical data on exercise of stock options and other factors to estimate the expected term of share-based awards. The Company also evaluates forfeitures periodically and adjusts accordingly. The expected volatility assumption is based on the unadjusted historical volatility of the Company s common stock. The risk-free interest rate assumption is based on U.S. Treasury interest rates at the time of grants. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards. 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.

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.

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 SFAS No. 34, Capitalization of Interest Costs (SFAS 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.

Results of Operations

Three and nine months ended September 30, 2008 compared to three and nine months ended September 30, 2007.

Product revenue

Product revenue for the quarter ended September 30, 2008 was $8,523,765, an increase of $1,240,636 or 17.0%, compared to $7,283,129 for the quarter ended September 30, 2007. Product revenue for the nine months ended September 30, 2008 was $24,770,230 an increase of $5,781,097 or 30.4%, compared to $18,989,133 for the nine months ended September 30, 2007.

Three Months Ended September 30,

			Increase (Decrease)	
	2008	**2007**	**$**	**%**
Joint Health	$ 4,676,247	$ 3,596,395	$ 1,079,852	30.0%
Ophthalmic	2,703,095	2,893,906	(190,811)	-6.6%
Veterinary	706,553	552,773	153,780	27.8%
Aesthetics	383,320	222,220	161,100	72.5%
Other	54,550	17,835	36,715	205.9%
	$ 8,523,765	$ 7,283,129	$ 1,240,636	17.0%

Nine Months Ended September 30,

			Increase (Decrease)	
	2008	**2007**	**$**	**%**
Joint Health	$ 13,563,901	$ 8,894,752	$ 4,669,149	52.5%
Ophthalmic	8,283,984	8,068,611	215,373	2.7%
Veterinary	2,427,570	1,682,870	744,700	44.3%
Aesthetics	399,370	224,220	175,150	78.1%
Other	95,405	118,680	(23,275)	-19.6%
	$ 24,770,230	$ 18,989,133	$ 5,781,097	30.4%

Our joint health products consist of ORTHOVISC, ORTHOVISC *mini* and MONOVISC, the latter two of which are currently only available outside the United States. Revenue from joint health products increased $1,079,852, or 30.0%, in the third quarter of 2008, and $4,669,149, or 52.5% for the first nine months of 2008. The improvement in joint health product revenue for the three and nine month periods ended September 30, 2008 were due to increases in both international and domestic ORTHOVISC revenue, as well as the launch of MONOVISC and ORTHOVISC *mini* in Europe and Turkey during the second quarter of 2008. Our U.S. joint health product revenue in the third quarter of 2008 totaled $3,113,165, compared to $2,496,393 in the same period last year, an increase of 24.7%. U.S. joint health product revenue for the nine months ended September 30, 2008 was $9,593,935, compared to $6,774,367 in the same period in 2007, a increase of 41.6%. These increases reflect DePuy Mitek s underlying sales increases to end-users of 23.9% and 30.2% for the three and nine month periods ended September 30, 2008 compared to the same periods in 2007, as well as some inventory growth by DePuy Mitek earlier in the year. International joint health product revenue in the third quarter of 2008 increased 42.1% to $1,563,082, from $1,100,002, in the third quarter last year. For the first nine

months of 2008, international joint health product revenue increased 87.2% to $3,969,966 from $2,120,384 in the same period of 2007. The increase in international revenue in both periods was due to increased product shipments to Turkey, Germany, Italy, Greece, Egypt, Hungary and Austria. We expect joint health product revenue to increase in 2008 compared to 2007, both domestically and internationally.

Our sales of ophthalmic products decreased $190,811, or 6.6%, in the third quarter of 2008 as compared with the same period last year. For the nine months ended September 30, 2008, ophthalmic product sales increased by $215,373, or 2.7% from the same period in 2007. The change in ophthalmic product sales for the three and nine month periods was primarily related to order timing and inventory building by our partners. For 2008, we only expect a slight increase in ophthalmic revenue compared to 2007.

Sales of HYVISC, our veterinary product, increased 27.8% and 44.3% for the three and nine months ended September 30, 2008 compared to the same periods last year. The increases for both periods were a combination of the increased sales people and resources used by our partner, Boehringer Ingelheim Vetmedica, to maintain its leading market share position, as well as its order patterns. We expect HYVISC sales to increase in 2008 compared to 2007.

Sales of ELEVESS, our aesthetics product, increased $161,100 or 72.5%, in the third quarter of 2008 as compared with the

same period last year. For the nine months ended September 30, 2008, ELEVESS sales increased by $175,150, or 78.1% from the same period in 2007. ELEVESS sales in the three and nine month periods ending September 30, 2007 were from Galderma, our former ELEVESS distribution partner. In July 2008, we entered into a distributor agreement with Artes Medical, Inc. for distribution of ELEVESS in the U.S. Shipments of commercial product and sample units commenced shortly after the signing of the distribution agreement, with product launch initiated in early August 2008. In October 2008, we entered into an exclusive agreement with Canderm Pharma, Inc., Canada s leading independent skincare company, to distribute and market ELEVESS throughout Canada. We expect shipments of commercial product and sample units to grow in the fourth quarter of 2008 and in 2009.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the quarter ended September 30, 2008 was $681,250 and comparatively flat for the same period last year. For the nine month period ended September 30, 2008, licensing, milestone and contract revenue was $2,043,753 compared to $2,213,855 in 2007. Licensing and milestone revenue includes the ratable recognition of the $27,000,000 up-front and milestone payments related to the JNJ agreement. These amounts are being recognized in income ratably over the ten-year expected life of the agreement, or $675,000 per quarter. For the three and nine month periods ended September 30, 2007, licensing and milestone revenue also included ratable recognition of an upfront payment for a former ELEVESS agreement with Galderma Pharma S.A., and reimbursements from Galderma for the extended European marketing trial of ELEVESS.

Product gross profit. Product gross profit for the three and nine month periods ended September 30, 2008 were $5,018,779 and $14,404,644, or 58.9% and 58.2% of product revenue, respectively. Product gross profit for the three and nine month periods ended September 30, 2007 were $4,144,822 and $10,334,123, or 56.9% and 54.4% of product revenue, respectively. The increases in product gross profit dollars for the three and nine month periods in 2008 were primarily due to higher product sales compared to the same periods in 2007. The increases in product gross margin percentages for the three and nine month periods in 2008 were primarily due to higher unit volume and a more favorable product mix compared to the same periods in 2007.

Research & development. Research and development expenses for the quarter ended September 30, 2008 were $1,801,561, an increase of $675,735, or 60.0%, compared to $1,125,826 for the quarter ended September 30, 2007. For the nine months ended September 30, 2008, research and development expenses were $4,954,520, an increase of $1,985,302, or 66.9%, compared to $2,969,218 for the same period in 2007. Research and development expenses for the three and nine month periods ended September 30, 2008 were primarily related to our U.S.-based clinical trials for MONOVISC, and post-approval clinical studies for MONOVISC and ORTHOVISC *mini* in Europe, manufacturing scale-up and related activities for MONOVISC and ELEVESS, as well as the development of our next-generation osteoarthritis product, CINGAL. The increases in research and development expenses for the three and nine month periods ended September 30, 2008 from the same periods in 2007 were primarily attributable to an increase in clinical trial expenses related to MONOVISC and ORTHOVISC products, engineering related expenses for the scale up of MONOVISC for commercial sales and additional headcount. We expect research and development expenses will increase in the future related to next generation joint health products, ELEVESS line extensions, and other research and development programs in the pipeline, but to decrease as a percentage of revenue commencing in 2009.

Selling, general & administrative. Selling, general and administrative expenses for the quarter ended September 30, 2008 were $2,567,000, an increase of $746,002, or 41.0%, compared to $1,820,998 for the quarter ended September 30,

2007. For the nine months ended September 2008, selling, general and administrative expenses were $8,515,772, an increase of $3,403,625, or 66.6%, compared to $5,112,147 for the same period in 2007. The increases in the quarter were primarily the result of marketing expenses associated with the launch of Elevess, increased personnel costs, and expenses related to the Company s new headquarters facility. The increases in the year-to-date period were primarily the result of marketing expenses associated with the launch of our new products, increased personnel costs, expenses related to the Company s new headquarters facility, and higher legal and consulting costs related to corporate governance, trademark matters, shareholders rights plan, and strategic programs. We expect that general and administrative expenses will increase for the remainder of 2008.

Interest income, net. Net interest income for the three months ended September 30, 2008 was $130,486, a decrease of $419,528, or 76.3%, compared to $550,014 for the same period last year. For the nine months ended September 30, 2008, net interest income was $477,767, a decrease of $1,214,855, or 71.8%, compared to $1,692,622 for the same period in 2007. The decreases in both periods were primarily attributable to lower interest rates as a result of Federal Reserve Bank reductions, movement to conservative U.S. treasury securities in mid-2007, and lower available cash and invested balances.

Income taxes. Provisions for income taxes were $357,751 and $634,033 for the three months ended September 30, 2008 and 2007, respectively. Provisions for income taxes were $921,182 and $1,797,377 for the nine months ended September 30, 2008 and 2007, respectively. The year-to-date effective tax rates for the provision 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 the 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.

LIQUIDITY AND CAPITAL RESOURCES

We require cash to fund our operating expenses and capital expenditures. We expect that our requirement for cash to fund these uses will increase as the scope of our operations expands. Prior to 2008, we funded our cash requirements from available cash and investments on hand. In 2008, we began borrowing from a line of credit with Bank of America to partially fund our Bedford facility capital project. At September 30, 2008, cash, cash equivalents, and investments totaled $35,368,244 compared to $39,405,543 at December 31, 2007.

Cash provided by operating activities was $2,220,091 for the nine months ended September 30, 2008 compared with $6,618,094 for the nine months ended September 30, 2007. This change was primarily due to lower net income, higher inventory requirements, and the timing of payments to vendors, partially offset by decreases in prepaid expenses.

Cash used in investing activities was $11,374,426 for the nine months ended September 30, 2008, compared to $9,760,170 for the nine months ended September 30, 2007. Cash used in investing activities was due to approximately $15 million in capital expenditures related to our new facility. This was partially offset by the maturity in February 2008 of a short-term tax exempt municipal bond of $3,500,000, which was purchased in February of 2007. We expect our capital expenditures in 2008 to increase primarily related to the build out of our new facility, which is our corporate headquarters, research and development, and manufacturing facility for the foreseeable future. We expect the new facility capital project to cost approximately $30 million (including interior construction, equipment, furniture and fixtures). Approximately $27 million has been spent since the inception of the project through September 30, 2008. The remaining costs are expected to be spent during the remainder of 2008 and early 2009. Construction commenced in May 2007 and validation of the facility is expected to occur starting in late 2008 into 2009. We expect to occupy our existing manufacturing facility through the end of 2009 and begin manufacturing at the Bedford facility at the beginning of 2010. There can also be no assurance that we will be successful in re-qualifying the new facility under FDA and European Union regulations.

Cash provided by financing activities was $8,619,010 and $2,134,282 for the nine months ended September 30, 2008 and 2007, respectively. On January 31, 2008, the Company entered into an unsecured credit facility for up to $16 million to finance a portion of the cost of the facility project. We have borrowed $8,000,000 through September 30, 2008. Cash provided by financing activities for both 2008 and 2007 included proceeds from exercises of stock options and any associated tax benefits.

Recent Accounting Pronouncements

In June 2008, the 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 rule.

In May 2008, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS 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 is not expected to 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.

Contractual Obligations and Other Commercial Commitments

We expect to incur significant capital investments related to the buildout of our new facility in Bedford, Massachusetts. Our plan is to fund the project with cash on hand and debt. On January 31, 2008, we entered into an unsecured credit agreement with Bank of America (the Credit Agreement). Under the Credit Agreement, Bank of America will make periodic loans to the Company through December 31, 2008 of up to a maximum principal amount at any time outstanding of $16,000,000. As of September 30, 2008, we had an outstanding debt balance of $8,000,000 under the Credit Agreement. 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. Construction of this new facility commenced in May 2007 and validation is expected to occur starting in late 2008 into 2009. To the extent that funds generated from our operations, together with our existing capital resources are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to our market risks since the date of our Annual Report on Form 10-K for the year ended December 31, 2007.

As of September 30, 2008, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments. Our investments consist of money market funds which are recorded at fair value and primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations.

Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk. Our investment portfolio of cash equivalents and our credit agreement are subject to interest rate fluctuations, but we believe this risk is immaterial due to the short-term nature of these investments and our ability to convert the existing debt to a fixed rate term loan.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended, (Exchange Act), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer

have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company s management, including our chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the third quarter of fiscal year 2008 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

On 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 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 1A. Risk Factors

There have been no material changes in the risk factors described in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007, except to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q relates to such risk factors. In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 6. Exhibits

Exhibit No.	Description
(11)	Statement Regarding the Computation of Per Share Earnings
*11.1	See Note 6 to the Financial Statements included herewith.
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Kevin W. Quinlan pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32)	Section 1350 Certifications
**32.1	Certification of Charles H. Sherwood, Ph.D. and Kevin W. Quinlan, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ANIKA THERAPEUTICS, INC.

November 6, 2008

By: /s/ KEVIN W. QUINLAN
Kevin W. Quinlan
Chief Financial Officer
(Principal Financial Officer)