

ANIKA THERAPEUTICS INC
Form 10-Q
May 04, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2009

- 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)

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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**

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 No

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of April 30, 2009, there were 11,435,872 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)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 40,426,703	\$ 43,193,655
Accounts receivable, net of reserves of \$60,000	6,483,017	5,418,421
Inventories	5,897,332	5,519,754
Current portion deferred income taxes	1,235,364	1,235,364
Prepaid expenses and other	858,931	463,284
Total current assets	54,901,347	55,830,478
Property and equipment, at cost	43,481,029	42,436,827
Less: accumulated depreciation	(10,508,898)	(10,190,144)
	32,972,131	32,246,683
Long-term deposits and other	357,603	506,787
Intangible asset, net	921,569	936,275
Deferred income taxes	6,213,980	6,300,665
Total Assets	\$ 95,366,630	\$ 95,820,888
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,036,244	\$ 2,375,340
Accrued expenses	2,612,902	2,325,219
Deferred revenue	2,732,018	2,732,293
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	43,544	
Total current liabilities	9,024,708	9,032,852
Other long-term liabilities	891,954	831,051
Long-term deferred revenue	10,124,996	10,800,001
Long-term debt	14,000,000	14,400,000
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, 11,435,872 shares issued and outstanding at March 31, 2009, 11,377,623 shares issued and outstanding at December 31, 2008	114,359	113,776
Additional paid-in-capital	42,905,914	42,861,229
Retained earnings	18,304,699	17,781,979
Total stockholders' equity	61,324,972	60,756,984
Total Liabilities and Stockholders' Equity	\$ 95,366,630	\$ 95,820,888

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 March 31,	
	2009	2008
Product revenue	\$ 8,519,073	\$ 7,867,529
Licensing, milestone and contract revenue	681,251	681,250
Total revenue	9,200,324	8,548,779
Operating expenses:		
Cost of product revenue	3,211,666	3,216,070
Research & development	2,194,308	1,508,340
Selling, general & administrative	3,034,982	3,068,616
Total operating expenses	8,440,956	7,793,026
Income from operations	759,368	755,753
Interest income, net	1,440	189,406
Income before income taxes	760,808	945,159
Provision for income taxes	238,088	327,601
Net income	\$ 522,720	\$ 617,558
Basic net income per share (Note 6):		
Net income	\$ 0.05	\$ 0.05
Basic weighted average common shares outstanding	11,366,545	11,225,282
Diluted net income per share (Note 6):		
Net income	\$ 0.05	\$ 0.05
Diluted weighted average common shares outstanding	11,496,518	11,612,720

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 Three Months Ended

(unaudited)

	March 31, 2009	March 31, 2008
Cash flows from operating activities:		
Net income	\$ 522,720	\$ 617,558
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	333,460	365,143
Amortization of premium on short-term investment		1,974
Stock-based compensation expense	200,357	323,289
Deferred income taxes	(68,404)	(106,002)
Provision for inventory reserve	62,604	
Tax benefit from exercise of stock options		(99,471)
Changes in operating assets and liabilities:		
Accounts receivable	(1,064,596)	2,505,771
Inventories	(440,182)	(978,715)
Prepaid expenses, other current and long-term assets	(246,463)	254,466
Accounts payable and accrued expenses	172,970	(3,793,866)
Deferred revenue	(675,280)	(681,251)
Income taxes payable	43,544	84,807
Other long-term liabilities	60,904	122,783
Net cash used in operating activities	(1,098,366)	(1,383,514)
Cash flows from investing activities:		
Proceeds from maturity of short-term investment		3,500,000
Purchase of property and equipment, net	(1,268,586)	(3,555,262)
Net cash used in investing activities	(1,268,586)	(55,262)
Cash flows from financing activities:		
Proceeds from long-term debt		4,000,000
Principal payment on debt	(400,000)	
Debt issuance costs		(87,721)
Proceeds from exercise of stock options		476,811
Tax benefit from exercise of stock options		99,471
Net cash provided by (used in) financing activities	(400,000)	4,488,561
Increase (decrease) in cash and cash equivalents	(2,766,952)	3,049,785
Cash and cash equivalents at beginning of year	43,193,655	35,903,569
Cash and cash equivalents at end of year	\$ 40,426,703	\$ 38,953,354
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 150,000	\$ 10,000
Interest paid for line of credit	\$ 61,924	\$

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; 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. 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 and Turkey. In the U.S. and several countries in Latin America, ORTHOVISC® is marketed by DePuy Mitek, Inc., 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 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC® -II, which is distributed by STAAR Surgical Company and ShellGel® for Cytosol Ophthalmics, 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. ELEVESS® is designed as a family of aesthetic dermatology products for facial wrinkles and scar remediation. Our initial ELEVESS® product is approved in the U.S., EU, Canada and certain countries in South America, and is manufactured by Anika. The Company is currently seeking new distribution partners for ELEVESS® both domestically and internationally. Products in development include next generation ELEVESS® line extension, and joint health related products.

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) government 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 March 31, 2009 and the results of its operations and cash flows for the three months ended March 31, 2009 and 2008.

Effective January 1, 2009 the Company adopted the 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. The retroactive adoption of this pronouncement reduced three months ended March 31, 2008 basic EPS from \$0.06 to \$0.05. See Note 6 for additional disclosures.

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, 2008. The results of operations for the three months ended March 31, 2009 are not necessarily indicative of the results to be expected for the year ending December 31, 2009, or any future periods.

3. Summary of Significant Accounting Policies

Use of Estimates

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 March 31, 2009 and December 31, 2008, cash equivalents consisted of money market funds invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, which approximates fair market value.

Fair Value Measurements

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 of our cash equivalents were \$34,201,231 and \$34,197,953 at March 31, 2009 and December 31, 2008, respectively, based on Level 1 inputs. Effective January 1, 2009, the Company adopted the provisions under SFAS No. 157 for valuation of nonfinancial assets and nonfinancial liabilities. The adoption of such provisions did not impact the Company's financial position, results of operations, or cash flows.

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, Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, and EITF 07-1 Accounting for Collaborative Arrangements, which became effective on January 1, 2009. Adoption of EITF 07-1 did not impact our financial statements for the three month periods ended March 31, 2009 and 2008.

Product Revenue

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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. For collaborative arrangements, the Company reports on a gross basis if it acts as a principal under the arrangements. Any payments received from (made to) other collaborators are accounted for based on existing applicable generally accepted accounting principles (GAAP) or, in the absence of other applicable GAAP, based on analogous authoritative accounting literature, or a reasonable, rational, and consistently applied accounting policy election.

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.

Long Lived Assets

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

The Company accounts for impairment of long-lived assets in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 establishes a uniform accounting model for long-lived assets to be disposed of. This Statement also requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset to estimated undiscounted future net cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. As of March 31, 2009, long-lived assets consisted of machinery, equipment, leasehold improvements and an intangible asset. The Company's intangible asset consists of its ELEVESS trade name. Significant assumptions underlying the recoverability of the intangible asset include: future cash flow, growth projections, product life cycle and useful life assumptions. The ultimate recoverability of the asset is dependent on the Company securing additional distributors, or directly commercializing the product. Recoverability of the carrying value of the asset may also be impacted by the outcome of the pending trade name opposition (Note 11). Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible asset. Effective January 1, 2009, the Company adopted Financial Accounting Standards Board (FASB) Staff Position (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 adoption did not have an impact on our financial position and results of operations for the three months ended March 31, 2009.

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 from 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 estimated useful life of the related facility and equipment.

Stock-Based Compensation

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

The Company accounts for stock-based compensation under 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. See Note 5 for additional disclosures.

Disclosures About Segments of an Enterprise and Related Information

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 March 31,	
	2009	2008
Joint Health	\$ 5,149,642	\$ 4,122,180
Ophthalmic	2,645,252	3,018,671
Veterinary	637,335	700,623
Aesthetics	50,094	3,000
Other	36,750	23,055
	\$ 8,519,073	\$ 7,867,529

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

	Percent of Product Revenue Three Months Ended March 31,	
	2009	2008
Depuy Mitek	43.0%	41.8%
Bausch & Lomb Incorporated	29.1%	35.3%
Boehringer Ingelheim Vetmedica	7.5%	8.9%
Biomeks	5.5%	0%
	85.1%	86.0%

As of March 31, 2009, six customers represented 89% of the Company's accounts receivable balance, and as of December 31, 2008, five customers represented 90% 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 months ended March 31, 2009 and 2008 are as follows:

	Three Months Ended March 31,			
	2009	Percent of Revenue	2008	Percent of Revenue
Geographic location:	Revenue		Revenue	
United States	\$ 6,135,564	72.0%	\$ 6,154,111	78.2%
Europe	1,483,368	17.4%	1,322,293	16.8%
Other	900,141	10.6%	391,125	5.0%
Total	\$ 8,519,073	100.0%	\$ 7,867,529	100%

Income Taxes

The Company accounts 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. 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 March 31, 2009, 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

On January 1, 2009, the Company adopted the provisions of FASB Statement of Financial Accounting Standard (SFAS) No. 141(R), Business Combinations (SFAS No. 141(R)), which revised SFAS No. 141, Business Combinations. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. The adoption did not have a material impact on the Company's financial statements.

In April 2009, the FASB issued the following new accounting standards:

- FASB Staff Position FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments, (FSP FAS 107-1 and APB 28-1). FSP FAS 107-1 and APB 28-1, amends FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, Interim Financial Reporting, to require those disclosures in all interim financial statements.
- FASB Staff Position FAS 157-4, Determining Whether a Market Is Not Active and a Transaction Is Not Distressed, (FSP FAS 157-4). FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures.
- FASB Staff Position FAS 115-2, FAS 124-2, and EITF 99-20-2, Recognition and Presentation of Other-Than-Temporary Impairments, (FSP FAS 115-2, FAS 124-2, and EITF 99-20-2). FSP FAS 115-2, FAS 124-2, and EITF 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities.

These standards are effective for periods ending after June 15, 2009. The Company is evaluating the impact that these standards will have on its financial statements.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Disclosures of additional new accounting pronouncements adopted during the first quarter of 2009 are discussed in Notes 3 and 6.

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 months ended March 31, 2009 and 2008 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	March 31, 2009	March 31, 2008
Risk-free interest rate	1.54%	2.39% - 2.82%
Expected volatility	59.39%	58.15% - 63.37%
Expected lives (years)	4	3 - 4
Expected dividend yield	0.00%	0.00%

The Company recorded \$200,357 and \$323,289 of share-based compensation expense for the three months ended March 31, 2009 and 2008, 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 Plan

The Company has reserved 1,500,000 shares of common stock for grants 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 annually over 3 to 4 years. 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.

Effective January 1, 2009 the Company adopted 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). FSP EITF 03-6-1 clarifies that share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments are included in the calculation of basic and diluted earnings per shares. Adoption of this pronouncement is retroactive to prior reporting periods, and reduced three months ended March 31, 2008 basic EPS from \$0.06 to \$0.05. Basic and diluted earnings per share for the three months ended March 31, 2009 and 2008 are as follows:

	Three Months Ended March 31,	
	2009	2008
Basic earnings per share		
Net income	\$ 522,720	\$ 617,558
Income allocated to participating securities	(2,384)	(3,068)
Income available to common stockholders	520,336	614,490
Basic weighted average common shares outstanding	11,366,545	11,225,282
Basic earnings per share	\$ 0.05	\$ 0.05
Diluted earnings per share		
Net income	\$ 522,720	\$ 617,558
Income allocated to participating securities	(2,358)	(2,966)
Income available to common stockholders	520,362	614,592
Weighted average common shares outstanding	11,366,545	11,225,282
Diluted potential common shares	129,973	387,438
Diluted weighted average common shares and potential common shares	11,496,518	11,612,720
Diluted earnings per share	\$ 0.05	\$ 0.05

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Equity awards of 1,021,404 and 314,850 shares were outstanding at March 31, 2009 and 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.

7. Inventories

Inventories consist of the following:

	March 31, 2009	December 31, 2008
Raw materials	\$ 2,666,002	\$ 2,556,588
Work-in-process	2,158,178	2,354,736
Finished goods	1,073,152	608,430
Total	\$ 5,897,332	\$ 5,519,754

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, under which the Company was provided with a revolving credit line through December 31, 2008 of up to a maximum principal amount at any time outstanding of \$16,000,000. The Company recorded approximately \$171,000 as deferred issuance costs, which is being amortized over the life of the long-term debt. The Company borrowed the maximum amount of \$16,000,000 in 2008 to finance its new facility construction and validation capital project. On December 31, 2008, the outstanding revolving credit loans were converted into a term loan with quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. Long-term debt principal payments over the next five years are \$1,600,000 per year.

The Company made its first quarterly principal payment of \$400,000 on March 31, 2009. The interest payable on our debt is determined based on either an interest rate based on LIBOR plus 0.75% or the lender's prime rate. As of March 31, 2009, the Company had an outstanding debt balance of \$15,600,000, at an interest rate of 1.31%. For the three months ended March 31, 2009, the Company capitalized interest expense of \$70,139 as part of construction in progress related to the Company's new facility build-out in accordance with SFAS No. 34, Capitalization of Interest Costs.

10. Income Taxes

Income tax expense was \$238,088 and \$327,601 for the three months ended March 31, 2009 and 2008, respectively. The effective tax rates were 31.3% and 34.7% for the three months ended March 31, 2009 and 2008, respectively. The decrease in effective tax rate was primarily due to an increase in the federal research tax credit. During the first quarter of 2009, there was no change to the Company's FIN 48 tax reserves. 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 previous 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 March 31, 2009, the carrying value of the intangible asset related to ELEVESS was \$921,569 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 the Food and Drug Administration (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, new distribution and revenue growth;
- our intention to increase market share for joint health products in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;
- our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals, and commercial launches;
- our expectations regarding HYVISC sales;
- our ability to license ELEVESS to a new distribution partner on terms favorable to the Company, if at all, or our ability to market ELEVESS on our own;
- 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 and our ability to obtain regulatory approvals 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 capital expenditures spending 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 ability to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and other sources, to the extent our current sources of funds are insufficient;
- our plans to address the FDA's Warning Letter and Form 483 Notice of Observations and the impact any associated regulatory action would have on our business and operations; 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 for the year ended December 31, 2008. 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, 2008 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors of new information, future events or other changes.

Management Overview

Anika Therapeutics, Inc. (Anika, the Company, we, us, or our) was incorporated in 1992 as a Massachusetts company. 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. HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT®, an HA based anti-adhesive for surgical applications. 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 and Turkey. In the U.S. and several countries in Latin America, 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 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC -II, which is distributed by STAAR

Surgical Company and Shellgel for Cytosol Ophthalmics, 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. ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles and scar remediation. Our initial ELEVESS product is approved in the U.S., the European Union (EU), Canada and certain countries in South America, and is manufactured by Anika. We are currently seeking new distribution partners for ELEVESS both domestically and internationally. Products in development include next generation joint health related products and ELEVESS line extension products.

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 24.9% for the three months ended March 31, 2009 compared with the same period in 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 60% of our revenue for the first three 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 2009 compared to 2008.

Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the three months ended March 31, 2009, sales of ophthalmic products contributed 31.1% of our product revenue. Ophthalmic sales decreased by 12.4% for the three month period in 2009 compared to the same period in 2008. The decrease in sales for the three month period was primarily due to order timing and inventory planning by our partners. Sales to Bausch & Lomb accounted for 93.7% of ophthalmic sales for the three months ended March 31, 2009, and contributed 29.1% of product revenue for the same period. We expect Ophthalmic sales in 2009 to be relatively flat compared to 2008.

Veterinary Business

Sales of HYVISC, our veterinary product for the treatment of equine osteoarthritis, contributed 7.5% of our product revenue for the three months ended March 31, 2009, and decreased by 9.0% compared to the same period in 2008. We expect HYVISC sales in 2009 to be relatively flat compared to 2008.

Anti-adhesion Business

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

INCERT, approved for sale in Europe and Turkey, is designed as a family of HA based products, 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.

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, and is approved in Europe, Canada, and the United States. In July 2008, we entered into a distributor agreement with Artes Medical, Inc. ("Artes") 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. Our distribution agreement with Artes was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

Research and Development

Products in development include next generation joint health related products. 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 and began sales in Europe during the second quarter of 2008, following a small, post marketing clinical study. In the U.S., we filed an Investigational Device Exemption, or an IDE application, with the FDA, and completed patient enrollment for our U.S. clinical trial in December 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 study and file an application for CE Mark 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 current manufacturing facility in Woburn, Massachusetts. 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 have provided the FDA with progress reports. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. The FDA did conduct a follow up inspection of the Company's Woburn facility and discussions are ongoing to address all issues and clear the Warning Letter as rapidly as possible. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems. 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 month periods ended March 31, 2009 and 2008, respectively, and our Annual Report on Form 10-K for the year ended December 31, 2008.

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, and EITF 07-1 Accounting for Collaborative Arrangements, which became effective on January 1, 2009. Adoption of EITF 07-1 did not impact our financial statements for the three month periods ended March 31, 2009 and 2008.

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

The Company accounts for stock-based compensation under the provisions SFAS 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 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 and stock appreciation rights include the exercise price of the award, the expected award term, the expected volatility of the Company's stock over the award's expected term, the risk-free interest rate over the award'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

The Company accounts 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. 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 March 31, 2009, 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.

Fair Value Measurements

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 of our cash equivalents were \$34,201,231 and \$34,197,953 at March 31, 2009 and December 31, 2008, respectively, based on Level 1 inputs. Effective January 1, 2009, the Company adopted the provisions under SFAS No. 157 for valuation of nonfinancial assets and nonfinancial liabilities. The adoption of such provisions did not impact the Company's financial position, results of operations, or cash flows.

Asset Valuation

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, investments, inventories, and intangible assets. We use a variety of factors to assess valuation, depending upon the asset. Accounts receivable are evaluated based upon the credit-worthiness of our customers, our historical experience, and the age of the receivable. The determination of whether unrealized losses on investments are other than temporary is based upon the type of investments held, market conditions, length of the impairment, magnitude of the impairment and ability to hold the investment to maturity. Should current market and economic conditions deteriorate, our ability to recover the cost of our investments may be impaired. The recoverability of inventories is based upon the types and levels of inventory held and forecasted demand. Should current market and economic conditions deteriorate, our actual recovery could be less than our estimate. Intangible assets are evaluated based upon the expected period the asset will be utilized, forecasted cash flows, and customer demand. Our intangible asset consists of our ELEVESS trade name. Significant assumptions underlying the recoverability of the intangible asset include: future cash flow, growth projections, product life cycle and useful life assumptions. The ultimate recoverability of the asset is dependent on us securing additional distributors, or directly commercializing the product. Recoverability of the carrying value of the asset may also be impacted by the outcome of the pending trade name opposition. Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible asset. On January 1, 2009, the Company adopted 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 adoption did not have an impact on our financial position and results of operations for the three months period ended March 31, 2009.

Property and Equipment

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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**Quarter ended March 31, 2009 compared to the quarter ended March 31, 2008.***Product revenue*

Product revenue for the quarter ended March 31, 2009 was \$8,519,073, an increase of \$651,544 or 8.3%, compared to \$7,867,529 for the quarter ended March 31, 2008.

	Quarter Ended March 31,		Increase (Decrease)	
	2009	2008	\$	%
Joint Health	\$ 5,149,642	\$ 4,122,180	\$ 1,027,462	24.9%
Ophthalmic	2,645,252	3,018,671	(373,419)	-12.4%
Veterinary	637,335	700,623	(63,288)	-9.0%
Aesthetics	50,094	3,000	47,094	1569.8%
Other	36,750	23,055	13,695	59.4%
	\$ 8,519,073	\$ 7,867,529	\$ 651,544	8.3%

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 \$1,027,462, or 24.9%, in the first quarter of 2009 from the first quarter of 2008. The improvement in joint health product revenue for the three months ended March 31, 2009 was due to increases in both international and domestic ORTHOVISC revenue, as well as the launch of MONOVISC in Europe during the second quarter of 2008. Our U.S. joint health product revenue in the first quarter of 2009 totaled \$3,663,203, compared to \$3,286,872 in the same period last year, an increase of 11.4%. The increase reflects DePuy Mitek's underlying sales increases to end-users of 30.8% for the three months ended March 31, 2009 compared to the same period in 2008. International joint health product revenue in the first quarter of 2009 increased 78.0% to \$1,486,439, from \$835,308 in the first quarter last year. The increase in international revenue in both periods was due to increased product shipments to France, Italy, Hungary, Turkey and Egypt. We expect joint health product revenue to increase in 2009 compared to 2008, both domestically and internationally.

Our sales of ophthalmic products decreased \$373,419, or 12.4%, in the first quarter of 2009 as compared with the same period last year. The change in ophthalmic product sales for the three month period was primarily related to order timing and inventory building by our partners. For 2009, we expect ophthalmic revenue to remain flat compared to 2008.

Sales of HYVISC, our veterinary product, decreased 9.0% for the three months ended March 31, 2009 compared to the same period last year. The decrease for the period was primarily due to order timing by our partner, Boehringer Ingelheim Vetmedica. We expect HYVISC revenue in 2009 to stay relatively flat from 2008.

Sales of ELEVESS, our aesthetics product, increased \$47,094, in the first quarter of 2009 as compared with the same period last year. ELEVESS revenue for both periods was primarily a result of our direct marketing efforts in the United States. Our distribution agreement with Artes Medical, Inc. was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the quarter ended March 31, 2009 was \$681,251 and comparatively flat for the same period last year. 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.

Product gross profit. Product gross profit for the three month period ended March 31, 2009 and 2008 were \$5,307,407 and \$4,651,459, or 62.3% and 59.1% of product revenue, respectively. The increase in product gross profit dollars for the three month period in 2009 was primarily due to higher product sales and more favorable product mix compared to the same period in 2008.

Research & development. Research and development expenses for the quarter ended March 31, 2009 was \$2,194,308, an increase of \$685,968, or 45.5%, compared to \$1,508,340 for the quarter ended March 31, 2008. Research and development expenses for the three month period ended March 31, 2009 was primarily related to our U.S.-based clinical trials for MONOVISC, U.S.-based post-approval clinical trial for ELEVESS, as well as the development of our next-generation osteoarthritis product, CINGAL. The increases in research and development expenses for the three month period ended March 31, 2009 from the same periods in 2008 was primarily attributable to an increase in clinical trial expenses related to MONOVISC and ELEVESS products, and development work related to CINGAL. We expect research and development expenses will increase in the future related to next generation joint health products, ELEVESS line extension products, 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 March 31, 2009 was \$3,034,982, a decrease of \$33,634, or 1.1%, compared to \$3,068,616 for the quarter ended March 31, 2008. The decrease in the quarter was primarily the result of decreased personnel related costs, partially offset by increase in strategic project activities. Prior year's spending also included non-recurring marketing expenses related to MONOVISC and ORTHOVISC mini launches. We expect that general and administrative expenses will increase for the remainder of 2009.

Interest income, net. Net interest income for the three months ended March 31, 2009 was \$1,440, a decrease of \$187,966, or 99.2%, compared to \$189,406 for the same period last year. The decrease was primarily attributable to lower interest rates as a result of Federal Reserve Bank reductions.

Income taxes. Provisions for income taxes were \$238,088 and \$327,601 for the three months ended March 31, 2009 and 2008, respectively. The effective tax rates for the provision were 31.3% and 34.7% for the three months ended March 31, 2009 and 2008, respectively. The decrease in effective tax rate was primarily due to an increase in federal research credit in 2009. During the first quarter of 2009, there was no change to the Company's FIN 48 tax reserves. 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, Massachusetts facility capital project. At March 31, 2009, cash and cash equivalents totaled \$40,426,703 compared to \$43,193,655 at December 31, 2008.

Cash used in operating activities was \$1,098,366 for the three months ended March 31, 2009 compared with \$1,383,514 for the three months ended March 31, 2008. This change was primarily due to lower net income and increase in accounts receivable, partially offset by the timing of payments to vendors.

Cash used in investing activities was \$1,268,586 for the three months ended March 31, 2009, compared to \$55,262 for the three months ended March 31, 2008. During the first three months in 2009, cash used in investing activities was due to approximately \$1.3 million in capital expenditures related to our new facility. During the first three months in 2008, cash used in investing activities was due to approximately \$3.6 million in capital expenditures related to our new facility, 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 2009 to decrease compared to 2008 as the new facility capital project winds down. We expect the new facility capital project to cost approximately \$32 million (including interior construction, equipment, furniture and fixtures). Approximately \$30 million has been spent since the inception of the project through March 31, 2009. The remaining costs are expected to be spent during the remainder of 2009. Construction commenced in May 2007 and validation of the facility is expected to be completed in 2009. We expect to occupy our existing manufacturing facility through the end of 2009 and begin manufacturing at the Bedford,

Massachusetts facility at the beginning of 2010. There can also be no assurance that we will be successful in qualifying the new facility under FDA and European Union regulations.

Cash used in financing activities was \$400,000 for the first three months in 2009 for our first principal payment on the long-term debt in the amount of \$400,000 on March 31, 2009. Cash provided by financing activities was \$4,488,561 for the first three months ended March 31, 2008 as a result of the \$4,000,000 borrowed under the Company's unsecured credit facility, and proceeds of approximately \$477,000 from employee stock option exercises.

Recent Accounting Pronouncements

On January 1, 2009, we adopted the following new accounting pronouncements:

FASB EITF Issue No. 07-1 (EITF 07-1), Accounting for Collaborative Arrangements . 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 analogous 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. EITF 07-1 was applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. Adoption of EITF 07-1 did not impact our financial statements for the three month periods ended March 31, 2009 and 2008.

FASB Staff Position EITF Issue 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities clarifies that share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments are included in the calculation of basic earnings per share. FSP EITF 03-6-1 is effective for the Company in 2009. The adoption of EITF Issue 03-6-1 did not have a material impact on the Company's earnings per share calculations.

FASB SFAS No. 141(R), Business Combinations (SFAS No. 141(R)), revised SFAS No. 141, Business Combinations. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. The adoption did not have a material impact on our financial statements.

FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3) 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. The adoption of this pronouncement did not impact our financial statements in the first quarter of 2009.

In April 2009, the FASB issued the following new accounting standards:

- FASB Staff Position FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, (FSP FAS 107-1 and APB 28-1). FSP FAS 107-1 and APB 28-1, amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements.
- FASB Staff Position FAS 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*, (FSP FAS 157-4). FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures.
- FASB Staff Position FAS 115-2, FAS 124-2, and EITF 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, (FSP FAS 115-2, FAS 124-2, and EITF 99-20-2). FSP FAS 115-2, FAS 124-2 and EITF 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities.

These standards are effective for periods ending after June 15, 2009. The Company is evaluating the impact that these standards will have on its financial statements.

Contractual Obligations and Other Commercial Commitments

We expect to incur significant capital investments related to the buildout of our new facility in Bedford, Massachusetts. This capital project is being financed 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 we were provided with a revolving credit line through December 31, 2008 of up to a maximum principal amount at any time outstanding of \$16,000,000. We borrowed the maximum amount of \$16,000,000 in 2008 to finance our new facility construction and validation capital project. On December 31, 2008, the outstanding revolving credit loans were converted into a term loan with quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. Long-term debt principal payments over the next five years are \$1,600,000 per year. We made our first principal payment on March 31, 2009 in the amount of \$400,000. Total debt outstanding was \$15,600,000 as of March 31, 2009. Construction of this new facility commenced in May 2007 and validation is expected to be

completed in 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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, 2008.

As of March 31, 2009, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107 and SFAS No. 161. Our investments consist of money market funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

Primary Market Risk Exposures

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Our primary market risk exposures are in the areas of interest rate risk and currency rate risk. We have two supplier contracts denominated in foreign currencies. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of changes in currency exchange rates for the two contracts on our financial statements were immaterial during the first quarter of 2009. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of March 31, 2009, we were subject to interest rate risk on \$15.6 million of variable rate debt. The interest payable on our debt is determined based on either an interest rate based on LIBOR plus 0.75% or the lender's prime rate and, therefore, is affected by changes in market interest rates. Based on the outstanding debt amount as of March 31, 2009, we would have a decrease in future annual cash flows of approximately \$149,000 for every 1% increase in the interest rate over the next twelve month period.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended, (Exchange Act), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the first quarter of fiscal year 2009 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 previous 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 March 31, 2009, the carrying value of the intangible asset related to ELEVESS was \$921,569. The Company does not believe any impairment of the asset has occurred.

Item 1A. Risk Factors

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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, 2008, 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, 2008, 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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.

May 4, 2009

By:

ANIKA THERAPEUTICS, INC.

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