

ANIKA THERAPEUTICS INC
Form 10-Q
November 03, 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 September 30, 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)

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 ☒ 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,

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

Large accelerated filer ☐

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 November 2, 2009, there were 11,437,814 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, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 38,540,295	\$ 43,193,655
Accounts receivable, net of reserves of \$92,500 and \$60,000 at September 30, 2009 and December 31, 2008, respectively	7,982,193	5,418,421
Inventories	6,951,192	5,519,754
Current portion deferred income taxes	1,235,364	1,235,364
Prepaid expenses and other	403,214	463,284
Total current assets	55,112,258	55,830,478
Property and equipment, at cost	44,875,631	42,436,827
Less: accumulated depreciation	(11,143,723)	(10,190,144)
	33,731,908	32,246,683
Long-term deposits and other	345,353	506,787
Intangible asset, net	892,157	936,275
Deferred income taxes	6,392,976	6,300,665
Total Assets	\$ 96,474,652	\$ 95,820,888
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,220,652	\$ 2,375,340
Accrued expenses	3,285,842	2,325,219
Deferred revenue	2,747,115	2,732,293
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	376,547	—
Total current liabilities	9,230,156	9,032,852
Other long-term liabilities	939,699	831,051
Long-term deferred revenue	8,774,996	10,800,001
Long-term debt	13,200,000	14,400,000
Commitments and contingencies (Note 9 and 12)		
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, 11,437,814 and 11,377,623 shares issued and outstanding at September 30, 2009, and December 31, 2008, respectively	114,378	113,776
Additional paid-in-capital	43,443,025	42,861,229
Retained earnings	20,772,398	17,781,979
Total stockholders' equity	64,329,801	60,756,984

Total Liabilities and Stockholders' Equity	\$	96,474,652	\$	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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Product revenue	\$ 10,087,130	\$ 8,523,765	\$ 27,376,966	\$ 24,770,230
Licensing, milestone and contract revenue	705,634	681,250	2,139,798	2,043,753
Total revenue	10,792,764	9,205,015	29,516,764	26,813,983
Operating expenses:				
Cost of product revenue	3,551,374	3,504,986	10,057,200	10,365,586
Research & development	2,382,146	1,801,561	6,862,683	4,954,520
Selling, general & administrative	2,842,991	2,567,000	8,613,525	8,515,772
Total operating expenses	8,776,511	7,873,547	25,533,408	23,835,878
Income from operations	2,016,253	1,331,468	3,983,356	2,978,105
Interest income (expense), net	(44,096)	130,486	(44,038)	477,767
Income before income taxes	1,972,157	1,461,954	3,939,318	3,455,872
Provision for income taxes	460,232	357,751	948,899	921,182
Net income	\$ 1,511,925	\$ 1,104,203	\$ 2,990,419	\$ 2,534,690
Basic net income per share:				
Net income	\$ 0.13	\$ 0.10	\$ 0.26	\$ 0.22
Basic weighted average common shares outstanding	11,385,679	11,329,422	11,379,128	11,294,928
Diluted net income per share:				
Net income	\$ 0.13	\$ 0.10	\$ 0.26	\$ 0.22
Diluted weighted average common shares outstanding	11,575,907	11,485,989	11,535,721	11,479,797

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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Anika Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
For the Nine Months Ended
(unaudited)

	September 30, 2009	September 30, 2008
Cash flows from operating activities:		
Net income	\$ 2,990,419	\$ 2,534,690
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	997,697	1,080,320
Amortization of premium on short-term investment	—	1,974
Stock-based compensation expense	707,389	1,072,538
Deferred income taxes	(247,801)	(268,162)
Provision for inventory reserve	168,593	26,172
Tax benefit from exercise of stock options	(27,349)	(229,920)
Changes in operating assets and liabilities:		
Accounts receivable	(2,563,772)	(733,736)
Inventories	(1,600,031)	(676,620)
Prepaid expenses, other current and long-term assets	221,504	821,267
Accounts payable and accrued expenses	777,956	(172,617)
Deferred revenue	(2,010,183)	(2,018,754)
Income taxes payable	403,896	520,033
Other long-term liabilities	108,648	262,906
Net cash provided by (used in) operating activities	(73,034)	2,220,091
Cash flows from investing activities:		
Proceeds from maturity of short-term investment	—	3,500,000
Purchase of property and equipment, net	(3,410,825)	(14,874,426)
Net cash used in investing activities	(3,410,825)	(11,374,426)
Cash flows from financing activities:		
Proceeds from long-term debt	—	8,000,000
Principal payment on debt	(1,200,000)	—
Debt issuance costs	—	(87,721)
Proceeds from exercise of stock options	3,150	476,811
Tax benefit from exercise of stock options	27,349	229,920
Net cash provided by (used in) financing activities	(1,169,501)	8,619,010
Decrease in cash and cash equivalents	(4,653,360)	(535,325)
Cash and cash equivalents at beginning of year	43,193,655	35,903,569
Cash and cash equivalents at end of year	\$ 38,540,295	\$ 35,368,244
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 680,000	\$ 10,000
Interest paid	\$ 168,177	\$ 112,518

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, Turkey, and Canada. 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 20 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 Hoya Surgical Optics, 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. Our aesthetic dermatology business is designed to have a family of products for facial wrinkles and scar remediation. Our initial aesthetic dermatology product is approved in the U.S., European Union (“EU”), Canada and certain countries in South America. This product is marketed in the U.S. by Coapt Systems, Inc. under the name of HYDRELLE™. Internationally, this product is marketed under the ELEVESS™ name. Products in development include a next generation HYDRELLE/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 September 30, 2009 and the results of its operations and cash flows for the three and nine months ended September 30, 2009 and 2008.

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 and nine months ended September 30, 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

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.

Subsequent Events

During the second quarter of 2009, the Company implemented Accounting Standards Codification 855, Subsequent Events (ASC 855), (formerly SFAS No. 165, Subsequent Events). This standard establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of ASC 855 did not impact our financial position or results of operations. We evaluated all significant events or transactions that occurred through November 3, 2009, the date we issued these financial statements. During this period, we did not have any material recognizable subsequent events.

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 Accounting Standards Codification 320, Investments - Debt and Equity Securities (ASC 320), (formerly 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, 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

Accounting Standards Codification 820, Fair Value Measurements and Disclosures (ASC 820), (formerly SFAS No. 157, Fair Value Measurements and Disclosures), 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 \$34,201,754 and \$34,197,953 at September 30, 2009 and December 31, 2008, respectively, based on Level 1 inputs. Effective January 1, 2009, the Company adopted the provisions under ASC 820 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.

During the second quarter of 2009, the Company implemented Accounting Standards Codification 825, Financial Instruments (ASC 825), (formerly FSP 107-1 and APB 28-1 Interim Disclosures about Fair Value of Financial Instruments). ASC 825 requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of this standard has resulted in the disclosure of the fair value of the Company's long term debt instrument on a quarterly basis. Since ASC 825 addresses disclosure requirements, the adoption of this ASC did not impact our financial position or results of operations. The carrying value of our debt instrument was \$14,800,000 at September 30, 2009. The estimated fair value of our debt instrument was approximately \$14,100,000 at September 30, 2009. The fair value was estimated using market observable inputs and interest rate measurements.

Revenue Recognition

The Company's revenue recognition policies are in accordance with Accounting Standards Codification 605, Revenue Recognition (ASC 605), and Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (formerly SEC SAB No. 101, Revenue Recognition in Financial Statements, as amended by SEC SAB No. 104, Revenue Recognition, EITF No. 00-21, Revenue Arrangements with Multiple Deliverables, and EITF No. 07-1 Accounting for Collaborative Arrangements, which became effective on January 1, 2009). Adoption of ASC 808 did not impact our financial statements for the three and nine month periods ended September 30, 2009 and 2008.

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 distributors' sales and recognized in the same period that our distributors' 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 ASC 605-25 (formerly EITF No. 00-21). Under ASC 605-25, 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.

On May 15, 2009, the Company entered into a Distribution Agreement ("the Agreement") with Coapt Systems, Inc. ("Coapt"). The agreement grants Coapt an exclusive, non-transferable right to market HYDRELLE™ in the United States. The Agreement contains a research and development component where the Company is reimbursed up to \$1,000,000 by Coapt for certain ongoing development related to the Company's aesthetic dermatology business. The development will be reimbursed to the Company based on a percentage of Coapt's net product sales to its customers. In addition, the Company will receive payments for the supply of HYDRELLE™ to Coapt and royalties on future Coapt net product sales to its customers. The Company accounted for the agreement pursuant to Accounting Standards Codification 605-25, Multiple Element Arrangements (ASC 605-25).

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. Account balances are charged-off against the allowance when the Company feels it is probable the receivable will not be recovered. Allowance for doubtful accounts was \$92,500 and \$60,000 at September 30, 2009 and December 31, 2008, respectively.

Long Lived Assets

The Company accounts for impairment of long-lived assets in accordance with Accounting Standards Codification 360, Property, Plant and Equipment (ASC 360), (formerly SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets). ASC 360 establishes a uniform accounting model for long-lived assets to be disposed of. This standard 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 September 30, 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. During the second quarter of 2009, the Company signed an exclusive distribution agreement with Coapt Systems, Inc. ("Coapt") for the distribution in the United States of Anika's aesthetic dermatology products for facial wrinkles. Coapt is marketing the Company's

existing product under the name HYDRELLE™, which caused the Company to perform a recoverability test in accordance with former SFAS No. 144 requirements in order to determine if the carrying value for the ELEVESS trade name was impaired. Our existing aesthetic dermatology product continues to be marketed outside of the U.S. under the ELEVESS™ name. The analysis concluded that the undiscounted cash flow exceeds the carrying value of the ELEVESS asset group. 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. Recoverability of the carrying value of the asset may also be impacted by the outcome of the pending trade name opposition (See Note 12). 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 Accounting Standards Codification 350, Intangibles – Goodwill and Other (ASC 350), (formerly FASB FSP No. 142-3, Determination of the Useful Life of Intangible Assets). ASC 350 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 former 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 and nine months ended September 30, 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 Accounting Standards Codification 835-20, Capitalization of Interest (ASC 835-20), (formerly SFAS No. 34, Capitalization of Interest Costs). 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

The Company accounts for stock-based compensation under the provisions of Accounting Standards Codification 718, Compensation – Stock Compensation (ASC 718), (formerly SFAS No. 123R, Share-Based Payment), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, 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

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 Accounting Standards Codification 280, Segment Reporting (ASC 280), (formerly 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,	
	2009	2008	2009	2008
Joint Health	\$6,136,101	\$4,676,247	\$16,854,428	\$13,563,901
Ophthalmic	2,705,897	2,703,095	7,832,072	8,283,984
Veterinary	584,709	706,553	1,833,644	2,427,570
Aesthetics	623,358	383,320	761,532	399,370
Other	37,065	54,550	95,290	95,405
	\$10,087,130	\$8,523,765	\$27,376,966	\$24,770,230

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

	Percent of Product Revenue Three Months Ended September 30,				Percent of Product Revenue Nine Months Ended September 30,			
	2009		2008		2009		2008	
Depuy Mitek	43.5	%	36.5	%	44.4	%	38.7	%
Bausch & Lomb Incorporated	25.2	%	29.8	%	27.0	%	31.1	%
Boehringer Ingelheim Vetmedica	5.8	%	8.3	%	6.7	%	9.8	%
Biomeks	6.0	%	6.4	%	5.7	%	4.9	%
	80.5	%	81.0	%	83.8	%	84.5	%

As of September 30, 2009 and 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 and nine months ended September 30, 2009 and 2008 are as follows:

	Three Months Ended September 30,			
	2009		2008	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:				
United States	\$7,317,404	72.5 %	\$6,062,837	71.1 %
Europe	1,923,502	19.1 %	1,515,983	17.8 %
Other	846,224	8.4 %	944,945	11.1 %
Total	\$10,087,130	100.0 %	\$8,523,765	100.0 %

	Nine Months Ended September 30,			
	2009		2008	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:				
United States	\$19,914,630	72.7 %	\$18,180,180	73.4 %
Europe	4,728,911	17.3 %	4,087,182	16.5 %
Other	2,733,425	10.0 %	2,502,868	10.1 %

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Total	\$27,376,966	100.0	%	\$24,770,230	100.0	%
-------	--------------	-------	---	--------------	-------	---

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 Accounting Standards Codification 740, Income Taxes (ASC 740), (formerly FIN 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109). 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 ASC 740 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, 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 Accounting Standards Codification 805, Business Combinations (ASC 805), (formerly SFAS No. 141(R), 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.

On June 3, 2009, the FASB approved the FASB Accounting Standards Codification, or the Codification, as the single source of authoritative nongovernmental Generally Accepted Accounting Principles, or GAAP, in the United States. The Codification is effective for interim and annual periods ending after September 15, 2009. Upon the effective date, the Codification will be the single source of authoritative accounting principles to be applied by all nongovernmental U.S. entities. All other accounting literature not included in the Codification will be nonauthoritative. The Codification does not change or alter existing GAAP and there was no impact on our consolidated financial position or results of operations.

In August 2009, the FASB issued Accounting Standards Update 2009-05, Fair Value Measurements and Disclosures (Topic 820). The purpose of this update is to clarify that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses either the quoted price of the identical liability when traded as an asset, quoted prices for similar liabilities or similar liabilities when traded as assets, or another valuation technique that is consistent with the principles of Topic 820. This guidance is effective upon issuance. There was no material impact to the Company from the adoption of this update.

In October 2009, the FASB issued Accounting Standards Update 2009-13, Multiple-Deliverable Revenue Arrangements – a consensus of the FASB Emerging Issues Task Force (Topic 605), which amends the revenue guidance under ASC 605. This update requires entities to allocate revenue in an arrangement using estimated selling prices of the delivered goods and services based on a selling price hierarchy. This guidance eliminates the residual method of revenue allocation and requires revenue to be allocated using the relative selling price method. This update is effective for fiscal years ending after June 15, 2010, and may be applied prospectively for revenue arrangements entered into or materially modified after the date of adoption or retrospectively for all revenue arrangements for all

periods presented. We are currently evaluating the impact this update will have on our consolidated financial statements.

Disclosures of additional new accounting pronouncements adopted during the first nine months 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 Accounting Standards Codification 320, Investments – Debt and Equity Securities (ASC 320), (formerly 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, 2009 and 2008 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	September 30, 2009	September 30, 2008
Risk-free interest rate	1.89%	2.39% - 2.82%
Expected volatility	61.03%	58.15% - 63.37%
Expected lives (years)	4	3-4
Expected dividend yield	0.00%	0.00%

	Nine Months Ended	
	September 30, 2009	September 30, 2008
Risk-free interest rate	1.54% - 1.89%	2.39% - 2.82%
Expected volatility	59.35% - 61.03%	58.15% - 63.37%
Expected lives (years)	4	3-4
Expected dividend yield	0.00%	0.00%

The Company recorded \$252,433 and \$707,389 of share-based compensation expense for the three and nine months ended September 30, 2009, respectively, for equity compensation awards. 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 equity compensation 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

On May 29, 2009, the Board of Directors approved the Company's Amended and Restated 2003 Stock Option and Incentive Plan, the ("2003 Plan"), to increase the number of shares subject to the 2003 Plan by 850,000. The amendment and restatement of the 2003 plan was approved by the Company's shareholders on June 5, 2009. This resulted in a total of 2,350,000 shares of common stock being reserved for issuance under the 2003 Plan. The Company issues new shares upon share option exercises 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 Accounting Standards Codification 260, Earnings Per Share (ASC 260), (formerly 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 Accounting Standards Codification 260-10, Earnings Per Share (ASC 260-10), (formerly FSP EITF 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities). ASC 260-10 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 share. Adoption of this pronouncement is retroactive to prior reporting periods. Basic and diluted earnings per share for the three and nine months ended September 30, 2009 and 2008 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Basic earnings per share				
Net income	\$1,511,925	\$1,104,203	\$2,990,419	\$2,534,690
Income allocated to participating securities	(6,753)	(7,176)	(11,170)	(15,423)
Income available to common stockholders	1,505,172	1,097,027	2,979,249	2,519,267
Basic weighted average common shares outstanding	11,385,679	11,329,422	11,379,128	11,294,928
Basic earnings per share	\$0.13	\$0.10	\$0.26	\$0.22
Diluted earnings per share				
Net income	\$1,511,925	\$1,104,203	\$2,990,419	\$2,534,690
Income allocated to participating securities	(6,647)	(7,079)	(11,021)	(15,176)
Income available to common stockholders	1,505,278	1,097,124	2,979,398	2,519,514
Weighted average common shares outstanding	11,385,679	11,329,422	11,379,128	11,294,928
Diluted potential common shares	190,228	156,567	156,593	184,869
Diluted weighted average common shares and potential common shares	11,575,907	11,485,989	11,535,721	11,479,797
Diluted earnings per share	\$0.13	\$0.10	\$0.26	\$0.22

Equity awards of 854,102 and 1,005,880 shares were outstanding for the three and nine months ended September 30, 2009, respectively, but not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive. Equity awards of 903,208 and 677,402 shares were outstanding for the three and nine months ended September 30, 2008, respectively, but not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive.

7. Inventories

Inventories consist of the following:

	September 30,	December 31,
	2009	2008
Raw materials	\$2,670,826	\$2,556,588
Work-in-process	3,181,543	2,354,736
Finished goods	1,098,823	608,430
Total		

\$6,951,192 \$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. Inventories increased from December 31, 2008 due to the planned inventory build up in preparation for moving some equipment to our Bedford manufacturing facility.

8. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2009	December 31, 2008
Payroll and benefits	\$ 1,480,093	\$ 1,380,901
Clinical trial costs	863,034	285,500
Professional fees	645,451	332,570
Other	297,264	326,248
Total	\$ 3,285,842	\$ 2,325,219

9. 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.

10. 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, in accordance with the Agreement, 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 three quarterly principal payments of \$400,000 on March 31, 2009, June 30, 2009 and September 30, 2009, respectively. The interest payable on our debt is determined, at the Company's option, based on either LIBOR plus 0.75% or the lender's prime rate. As of September 30, 2009, the Company had an outstanding debt balance of \$14,800,000, at an interest rate of 1.05%. The Company capitalized interest expense of \$0 and \$98,183 for the three and nine months ended September 30, 2009, respectively, as part of construction in progress related to the Company's new facility build-out in accordance with ASC 835-20, Capitalization of Interest Costs.

11. Income Taxes

Income tax expense was \$460,232 and \$357,751 for the three months ended September 30, 2009 and 2008, respectively. Income tax expense was \$948,899 and \$921,182 for the nine months ended September 30, 2009 and 2008, respectively. The effective tax rates were 23.3% and 24.5% for the three months ended September 30, 2009 and 2008, respectively. The effective tax rates were 24.1% and 26.7% for the nine months ended September 30, 2009 and 2008, respectively. The decrease in effective tax rates was primarily due to increases in research tax credits. During the first nine months of 2009, there was no change to the Company's ASC 740 tax reserves. Our U.S. federal income

tax returns for the years 2005, 2006, 2007, and 2008 remain subject to examination, and our state income tax returns for the years 2006, 2007 and 2008 remain subject to examination.

12.

Trademark Opposition

On December 12, 2007, Colbar Lifescience Ltd. (“Colbar”), 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 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, 2009, the carrying value of the intangible asset related to ELEVESS was \$892,157 and the Company does not believe any impairment of the asset has occurred. Please also refer to Note 3 under “Long-lived Assets” for more discussions on the ELEVESS trade name intangible asset.

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;
 - the development of possible new products;
 - our ability to achieve or maintain compliance with laws and regulations;
- the timing of and/or receipt of the Food and Drug Administration ("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 ability, and the ability of our distribution partner, to market our aesthetic dermatology product;
- our expectations regarding our joint health products, including expectations regarding new products, expanded uses of existing products, new distribution and revenue growth;
- our intention to increase market share for joint health products in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;
- our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals, and commercial launches;
 - our expectations regarding HYVISC sales;
- our expectations regarding the development and commercialization of INCERT, and the market potential for INCERT;

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

- our expectations regarding HYDRELLE product sales in the U.S.;
 - our ability to license our aesthetics product to new distribution partners outside of the United States;
 - 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 our U.S. MONOVISC trials and the timing of the related premarket approval (“PMA”) filing with the FDA;
-

- our expectations regarding the commencement of our clinical trial for CINGAL and our ability to obtain regulatory approvals for CINGAL;
- our expectations regarding our existing aesthetics product's line extensions;
- 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 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,” and other expressions that are predictions of or indicate events and trends and which do not relate to historical matters, also identify forward-looking statements. You should not rely on forward looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 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, INCERT®, an HA based anti-adhesive for surgical applications, ORTHOVISC® mini, a treatment for osteoarthritis targeting small joints available in Europe, and MONOVISC™, a single-injection osteoarthritis product based on our proprietary cross-linking technology and available in Europe, Turkey, and Canada. 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 20 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 Hoya Surgical Optics, 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. Our aesthetic dermatology business is designed to have a family of products for facial wrinkles and scar remediation. Our initial aesthetic dermatology product is approved in the U.S., EU, Canada and certain countries in South America. This product is marketed in the U.S. by Coapt Systems, Inc. (“Coapt”) under the name of HYDRELLE™. Internationally, this product is marketed under the ELEVESS™ name. Products in development include a next generation HYDRELLE/ELEVESS™ line extension, and joint health related products.

Osteoarthritis Business

Our joint health products include ORTHOVISC, ORTHOVISC mini, and MONOVISC. ORTHOVISC mini, and MONOVISC are our two newest joint health products and became available during the second quarter of 2008. Our revenue from joint health products has increased 31.2% and 24.3% for the three and nine months ended September 30, 2009 compared with the same periods in 2008. This increase 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 62% of our product 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 2009 compared to 2008.

Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the three and nine months ended September 30, 2009, sales of ophthalmic products contributed 26.8% and 28.6% of our product revenue, respectively. Ophthalmic sales were relatively flat for the three month period in 2009 compared to the same period in 2008. Ophthalmic sales decreased by 5.5% for the nine month period in 2009 compared to the same period in 2008. The decrease in sales for the nine month period was primarily due to order timing and inventory management by our partners. Sales to Bausch & Lomb accounted for 94.0% and 94.5% of ophthalmic sales for the three and nine months ended September 30, 2009, respectively, and contributed 25.2% and 27.0% of product revenue for the same periods.

Veterinary Business

Sales of HYVISC, our veterinary product for the treatment of equine osteoarthritis, contributed 5.8% and 6.7% of our product revenue for the three and nine months ended September 30, 2009, respectively, and decreased by 17.2% and 24.5% compared to the same periods in 2008. We believe the decrease for these periods was primarily due to inventory management by our partner, Boehringer Ingelheim Vetmedica. We expect HYVISC sales in 2009 will be lower than in 2008.

Anti-adhesion Business

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

Our aesthetic dermatology business is designed to have a family of products for facial wrinkles and scar remediation, and is intended to compete with collagen-based and other HA-based products currently on the market. Our initial aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and is approved in Europe, Canada, the U.S. and certain countries in South America. This product is marketed in the U.S. by Coapt under the name of HYDRELLE™. Our distribution agreement with Coapt was signed in May 2009. Coapt began selling the product in the third quarter of 2009. Internationally the product is marketed under the ELEVESS™ name. We continue to focus on the development and expansion of the product in additional countries.

Research and Development

Products in development include MONOVISC for U.S. marketing approval, and additional next generation joint health related products. Our first next generation osteoarthritis product is MONOVISC, 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. 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 the clinical segment of the U.S. MONOVISC pivotal trial in June 2009, and a follow-on retreatment study in September 2009. We are currently analyzing the data and expect to complete a PMA filing with the FDA before the end of 2009. Our second single-injection osteoarthritis product under development 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.

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 an initial 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. We expect to have an additional inspection of the Woburn facility in the near future. 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

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 our Quarterly Reports on Form 10-Q for the three and nine month periods ended September 30, 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 Accounting Standards Codification 605, Revenue Recognition (ASC 605), and Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (formerly the SEC SAB No. 101, Revenue Recognition in Financial Statements, as amended by SEC SAB No. 104, Revenue Recognition, and EITF No. 00-21, Revenue Arrangements with Multiple Deliverables, and EITF No. 07-1 Accounting for Collaborative Arrangements), which became effective on January 1, 2009. Adoption of ASC 808 did not impact our financial statements for the three and nine month periods ended September 30, 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 of Accounting Standards Codification 718, Compensation – Stock Compensation (ASC 718), (formerly SFAS No. 123R, Share-Based Payment), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, 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 Accounting Standards Codification 740, Income Taxes (ASC 740), (formerly FIN 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109). 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 ASC 740 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, 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.

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. During the second quarter of 2009, we signed an exclusive distribution agreement with Coapt for the distribution in the United States of Anika's aesthetic dermatology products for facial wrinkles. Coapt is marketing this product under the name HYDRELLE™, which caused the Company to perform a recoverability test in accordance with SFAS No. 144 requirements in order to determine if the carrying value for the ELEVESS trade name was impaired. Our existing aesthetic dermatology product continues to be marketed outside of the U.S. under the ELEVESS™ name. The analysis concluded that the undiscounted cash flow exceeds the carrying value of the ELEVESS asset group. 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. 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. As of September 30, 2009, the carrying value of the intangible assets related to ELEVESS was \$892,157.

On January 1, 2009, the Company adopted Accounting Standards Codification 350, Intangibles – Goodwill and Other (ASC 350), (formerly FSP No. 142-3, Determination of the Useful Life of Intangible Assets). ASC 350 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 former 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 and nine month periods ended September 30, 2009.

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 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 Accounting Standards Codification 835-20, Capitalization of Interest (ASC 835-20), (formerly SFAS No. 34, Capitalization of Interest Costs). 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, 2009 compared to three and nine months ended September 30, 2008.

Product Revenue

Product revenue for the quarter ended September 30, 2009 was \$10,087,130, an increase of 18.3%, compared to the third quarter of 2008. Product revenue for the nine months ended September 30, 2009 was \$27,376,966, an increase of 10.5%, compared to the nine months ended September 30, 2008.

	Three Months Ended		Increase (Decrease)		
	September 30, 2009	2008	\$	%	
Joint Health	\$6,136,101	\$4,676,247	\$1,459,854	31.2	%
Ophthalmic	2,705,897	2,703,095	2,802	0.1	%
Veterinary	584,709	706,553	(121,844)	-17.2	%
Aesthetics	623,358	383,320	240,038	62.6	%
Other	37,065	54,550	(17,485)		NM
	\$10,087,130	\$8,523,765	\$1,563,365	18.3	%

NM – Not meaningful

	Nine Months Ended September 30,		Increase (Decrease)		
	2009	2008	\$	%	
Joint Health	\$16,854,428	\$13,563,901	\$3,290,527	24.3	%
Ophthalmic	7,832,072	8,283,984	(451,912)	-5.5	%
Veterinary	1,833,644	2,427,570	(593,926)	-24.5	%
Aesthetics	761,532	399,370	362,162	90.7	%
Other	95,290	95,405	(115)	NM	
	\$27,376,966	\$24,770,230	\$2,606,736	10.5	%

NM – Not meaningful

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 \$1,459,854, or 31.2%, in the third quarter of 2009 from the third quarter of 2008. For the nine months ended September 30, 2009, joint health product sales increased \$3,290,527, or 24.3%, compared with the same period in 2008. The improvement in joint health product revenue for the three and nine months ended September 30, 2009 was primarily due to increases in ORTHOVISC revenue. Our U.S. joint health product revenue in the third quarter of 2009 totaled \$4,388,677, compared to \$3,113,165 in the same period last year, an increase of 41%. Our U.S. joint health product revenue for the nine months ended September 30, 2009 totaled \$12,148,161, compared to \$9,593,935 in the same period last year, an increase of 26.6%. The increase reflects DePuy Mitek's underlying volume driven sales increases to end-users of 34.6% and 32.8% for the three and nine months ended September 30, 2009 compared to the same periods in 2008, as a result of their continued marketing efforts. International joint health product revenue in the third quarter of 2009 increased 11.8% to \$1,747,424, from \$1,563,082 in the third quarter last year. International joint health product revenue in the nine months ended September 30, 2009 increased 18.5% to \$4,706,267, from \$3,969,966 in the same period last year. The increase in international revenue during the three and nine months ended September 30, 2009 was led by increased product shipments to France, Hungary, Canada, and Turkey. We expect joint health product revenue to increase in 2009 compared to 2008, both domestically and internationally.

Our sales of ophthalmic products increased \$2,802, or 0.1%, and decreased \$451,912, or 5.5% for the three and nine months ended September 30, 2009, respectively, as compared with the same periods last year. The change in ophthalmic product sales for the three and nine month period was primarily related to order timing and inventory management by our partners.

Sales of HYVISC, our veterinary product, decreased 17.2% and 24.5% for the three and nine months ended September 30, 2009 compared with the same periods last year. We believe the decrease for the period was primarily due to inventory management by our partner, Boehringer Ingelheim Vetmedica. We expect HYVISC revenue in 2009 to be lower than in 2008.

Sales of our aesthetics products increased \$240,038 and \$362,162 for the three and nine months ended September 30, 2009 as compared to the same periods last year. The increase in revenue for both periods was primarily due to the commencement of sales in the third quarter to our new United States distributor, Coapt Systems, Inc. Coapt is marketing the product in the U.S. under the brand name HYDRELLE™. In key markets outside of the U.S., we continue to seek marketing and distribution partners to commercialize ELEVESS.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the quarter ended September 30, 2009 was \$705,634 compared to \$681,250 for the same period last year. For the nine month period ended September 30, 2009, licensing, milestone and contract revenue was \$2,139,798 compared to \$2,043,753 for the same period last year. The increase was due to a new product development contract with an existing distributor. Licensing and milestone revenue includes the ratable recognition of \$27,000,000 in 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 through the fourth quarter of 2013.

Product gross profit. Product gross profit for the three and nine month periods ended September 30, 2009 were \$6,535,756 and \$17,319,766, or 64.8% and 63.3% of product revenue, respectively. 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. The increases in product gross profit dollars and margin for the three and nine month periods in 2009 were primarily due to increased sales of our more profitable joint health products resulting in a more favorable product mix compared to the same periods in 2008, and increased manufacturing activity in our Woburn facility to build inventory in preparation for moving our operations to the Bedford facility. We expect a small decline in gross margin in the fourth quarter due to lower manufacturing activity while the equipment is re-installed in Bedford.

Research & development. Research and development expenses for the quarter ended September 30, 2009 were \$2,382,146, an increase of \$580,585, or 32.2%, compared to \$1,801,561 for the quarter ended September 30, 2008. For the nine months ended September 30, 2009, research and development expenses were \$6,862,683, an increase of \$1,908,163, or 38.5%, compared to \$4,954,520 for the same period in 2008. The increases in research and development expenses for the three and nine month periods were primarily related to our ongoing U.S.-based clinical trials for MONOVISC, the post-marketing aesthetics dermatology study in people of color, manufacturing validation activities at our Bedford facility, as well as other continuing new product development projects. We expect research and development spending will increase at a slower rate in the future related to next generation joint health products, our aesthetics product line extension products, and other research and development programs in the pipeline.

Selling, general & administrative. Selling, general and administrative expenses for the quarter ended September 30, 2009 were \$2,842,991, an increase of \$275,991, or 10.8%, compared to \$2,567,000 for the quarter ended September 30, 2008. For the nine months ended September 30, 2009, selling, general and administrative expenses were \$8,613,525, an increase of \$97,753, or 1.1% compared to \$8,515,772 for the same period in 2008. The increases in both the three and nine month periods were primarily the result of higher professional fees, which more than offset a decrease in marketing expenses. Operating expenses related to the Bedford facility were flat year-over-year. The prior year's spending included additional marketing expenses as a result of the MONOVISC and ORTHOVISC mini launches product launches in Europe. We expect general and administrative expenses in 2009 to be higher than 2008.

Interest income (expense), net. Net interest expense for the three months ended September 30, 2009 was \$44,096 compared to a net interest income of \$130,486 for the same period last year. For the nine months ended September 30, 2009, net interest expense was \$44,038, compared to a net interest income of \$477,767 for the same period last year. The decrease was primarily attributable to lower interest rates as a result of the current rate environment. The net expense for the three months ended September 30, 2009 represents interest expense related to our facilities' asset retirement obligations, and the interest expense on our outstanding debt balance, which was capitalized during the construction/validation stages prior to July 1, 2009.

Income taxes. Provisions for income taxes were \$460,232 and \$357,751 for the three months ended September 30, 2009 and 2008, respectively. Provisions for income taxes were \$948,899 and \$921,182 for the nine months ended September 30, 2009 and 2008, respectively. The effective tax rates for the nine months ended September 30, 2009 and 2008 were 24.1% and 26.7%, respectively. The decrease in effective tax rates was primarily due to an increase in research credits in 2009. During the nine months ended September 30, 2009, there was no change to the Company's ASC 740 tax reserves. Our U.S. federal income tax returns for the years 2005, 2006, 2007, and 2008 remain subject to examination, and our state income tax returns for the years 2006, 2007 and 2008 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 operations will increase as the scope of our operations expand. After 2009, we expect our capital expenditures to significantly decrease. Prior to 2008, we funded our cash requirements from operations as well as from existing cash and investments on hand. In 2008, we borrowed \$16 million under a line of credit with Bank of America to partially fund our Bedford, Massachusetts facility capital project. At September 30, 2009, cash and cash equivalents totaled \$38,540,295 compared to \$43,193,655 at December 31, 2008, and working capital totaled \$45,882,102 and \$46,797,626, respectively. The company believes that its existing cash and cash equivalents as of September 30, 2009, and the company's future cash flow from operations, are sufficient to meet the cash requirements of its businesses for the foreseeable future.

Cash used in operating activities was \$73,034 for the nine months ended September 30, 2009 compared with cash provided by operating activities of \$2,220,091 for the nine months ended September 30, 2008. This change was primarily due to increases in inventory and accounts receivable working capital needs, partially offset by the timing of

payments to vendors.

Cash used in investing activities was \$3,410,825 for the nine months ended September 30, 2009, compared to \$11,374,426 for the nine months ended September 30, 2008. During the first nine months in 2009, cash used in investing activities was related to our Bedford facility capital expenditures. During the first nine months in 2008, cash used in investing activities was due to approximately \$14.9 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 2010 to decrease compared to 2009 as the new facility capital project winds down. The new facility capital project cost is approximately \$33 million (including interior construction, equipment, furniture and fixtures). Construction commenced in May 2007 and validation of the facility is expected to be completed in 2010. At September 30, 2009, there was approximately \$1 million remaining to be spent to complete the project. We expect to begin manufacturing at the Bedford, Massachusetts facility in late 2009. There can 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 \$1,169,501 for the first nine months in 2009, which was due to our principal payments on the long-term debt in the amount of \$1.2 million. This was partially offset by small amounts from employee stock exercise proceeds and related tax benefits. Cash provided by financing activities was \$8,619,010 for the first nine months ended September 30, 2008 as a result of the \$8,000,000 borrowed under the Company's unsecured credit facility, and proceeds of \$476,811 from employee stock option exercises, and a tax benefit from the exercise of stock options of \$229,920. This was partially offset by debt issuance costs of \$87,721.

Recent Accounting Pronouncements

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

Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (formerly EITF No. 07-1 Accounting for Collaborative Arrangements). ASC 808 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. ASC 808 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, ASC 808 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to ASC 605 (formerly EITF No. 01-9). ASC 808 was applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. Adoption of ASC 808 did not impact our financial statements for the three and nine month periods ended September 30, 2009 and 2008.

Accounting Standards Codification 260-10, Earnings Per Share (ASC 260), (formerly FSP EITF 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. ASC 260 is effective for the Company in 2009. The adoption of ASC 260-10 did not have a material impact on the Company's earnings per share calculations.

Accounting Standards Codification 805, Business Combinations (ASC 805), (formerly SFAS No. 141(R), Business Combinations, which revised SFAS No. 141, Business Combinations). The standard 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.

Accounting Standards Codification 350, Intangibles – Goodwill and Other (ASC 350), (formerly FSP No. 142-3, Determination of the Useful Life of Intangible Assets), 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 former SFAS No. 142, Goodwill and Other Intangible Assets. The intent of this standard is to improve the consistency between the useful life of a recognized intangible asset under former SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under ASC 805, Business Combinations, and other U.S. generally accepted accounting principles. The adoption of this pronouncement did not impact our financial statements in the three and nine months ended September 30, 2009.

On June 3, 2009, the FASB approved the FASB Accounting Standards Codification, or the Codification, as the single source of authoritative nongovernmental Generally Accepted Accounting Principles, or GAAP, in the United States. The Codification is effective for interim and annual periods ending after September 15, 2009. Upon the effective date,

the Codification will be the single source of authoritative accounting principles to be applied by all nongovernmental U.S. entities. All other accounting literature not included in the Codification will be nonauthoritative.. The Codification does not change or alter existing GAAP and there was no impact on our consolidated financial position or results of operations.

Effective last quarter, we implemented Accounting Standards Codification 855, Subsequent Events (ASC 855), (formerly SFAS No. 165, Subsequent Events). This standard establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of ASC 855 did not impact our financial position or results of operations. We evaluated all events or transactions that occurred through November X, 2009, the date we issued these financial statements. During this period we did not have any material recognizable subsequent events.

Effective last quarter, the Company also implemented Accounting Standards Codification 825, Financial Instruments (ASC 825), (formerly FSP 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments). The adoption of this standard has resulted in the disclosure of the fair value of the Company's long term debt instrument on a quarterly basis. Since ASC 825 addresses disclosure requirements, the adoption of this ASC did not impact our financial position or results of operations. The carrying value of our debt instrument was \$14,800,000 at September 30, 2009. The estimated fair value of our debt instrument was approximately \$14,100,000 at September 30, 2009. The fair value was estimated using market observable inputs and interest rate measurements.

In August 2009, the FASB issued Accounting Standards Update 2009-05, Fair Value Measurements and Disclosures (Topic 820). The purpose of this update is to clarify that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses either the quoted price of the identical liability when traded as an asset or quoted prices for similar liabilities or similar liabilities when traded as assets or another valuation technique that is consistent with the principles of Topic 820. This guidance is effective upon issuance. There was no material impact to the Company from the adoption of this update.

In October 2009, the FASB issued Accounting Standards Update 2009-13, Multiple-Deliverable Revenue Arrangements – a consensus of the FASB Emerging Issues Task Force (Topic 605), which amends the revenue guidance under ASC 605. This update requires entities to allocate revenue in an arrangement using estimated selling prices of the delivered goods and services based on a selling price hierarchy. This guidance eliminates the residual method of revenue allocation and requires revenue to be allocated using the relative selling price method. This update is effective for fiscal years ending after June 15, 2010, and may be applied prospectively for revenue arrangements entered into or materially modified after the date of adoption or retrospectively for all revenue arrangements for all periods presented. We are currently evaluating the impact this update will have on our consolidated financial statements.

Contractual Obligations and Other Commercial Commitments

We have made significant capital investments related to the build-out and validation of our facility in Bedford, Massachusetts. This capital project has been financed with cash on hand and the proceeds of a \$16,000,000 unsecured credit agreement with Bank of America (the "Credit Agreement") entered into on January 31, 2008. We borrowed the maximum amount of \$16,000,000 in 2008, initially under an interest only line of credit, and on December 31, 2008 the balance was 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 commenced making quarterly principal payments in 2009. Total debt outstanding was \$14,800,000 as of September 30, 2009. Construction of this facility commenced in May 2007 and validation is expected to be completed in 2010. 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, 2008.

As of September 30, 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 Accounting Standards Codification 825, Financial Instruments (ASC 825), (formerly SFAS No. 107, Disclosures about Fair Value

of Financial Instruments) and Accounting Standards Codification 815, Derivatives and Hedging (ASC 815), (formerly SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities). 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

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 nine months of 2009. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of September 30, 2009, we were subject to interest rate risk on \$14.8 million of variable rate debt. The interest payable on our debt is determined, at the Company's option, based on either 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 September 30, 2009, we would have a decrease in future annual cash flows of approximately \$141,333 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 third 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

On December 12, 2007, Colbar Lifescience Ltd. (“Colbar”), a subsidiary of Johnson & 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 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, 2009, the carrying value of the intangible asset related to ELEVESS was \$892,157. The Company does not believe any impairment of the asset has occurred.

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

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, 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
(10)	Material Contracts
10.1	Employment Agreement, dated as of September 10, 2009, between Anika Therapeutics, Inc. and Frank J. Luppino, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
10.2	Employment Agreement, dated as of September 10, 2009, between Anika Therapeutics, Inc. and William J. Mrachek, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
(11)	Statement Regarding 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.
<hr/>	
*	Filed herewith.
**	Furnished herewith.
<hr/>	

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 3, 2009

By:

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