

ANIKA THERAPEUTICS INC
Form 10-Q
November 09, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒

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

For the quarterly period ended September 30, 2007

☐

**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
(IRS Employer Identification No.)

160 New Boston Street, Woburn, Massachusetts
(Address of Principal Executive Offices)

01801
(Zip Code)

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

(781) 932-6616

(Registrant's telephone number, including area code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Securities Exchange Act (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

Indicate the number of shares outstanding of each of the issuer's class of common stock, as of the last practicable date. At October 26, 2007 there were 11,169,522 outstanding 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, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 46,159,638	\$ 47,167,432
Short-term investment	3,508,992	
Accounts receivable, net of reserves of \$49,724 at September 30, 2007 and December 31, 2006	4,965,946	3,509,508
Inventories	4,712,631	5,395,596
Current portion deferred income taxes	1,312,901	1,312,901
Prepaid expenses and other receivables	510,950	220,445
Total current assets	61,171,058	57,605,882
Property and equipment, at cost	22,940,274	13,255,240
Less: accumulated depreciation	(10,756,296)	(10,237,232)
	12,183,978	3,018,008
Long-term deposits and other	349,310	193,050
Deferred income taxes	7,525,066	7,296,689
Total Assets	\$ 81,229,412	\$ 68,113,629
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,184,935	\$ 965,180
Accrued expenses	2,355,160	1,573,835
Deferred revenue	3,257,413	2,905,099
Income taxes payable	383,336	17,253
Total current liabilities	10,180,844	5,461,367
Other long-term liabilities	268,243	64,525
Long-term deferred revenue	18,157,404	17,099,712
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at September 30, 2007 and December 31, 2006		
Common stock, \$.01 par value; 30,000,000 shares authorized, 11,169,522 shares issued and outstanding at September 30, 2007, 10,772,654 shares issued and outstanding at December 31, 2006	111,695	107,727

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Additional paid-in-capital	40,031,838	37,262,768
Retained earnings	12,479,388	8,117,530
Total stockholders' equity	52,622,921	45,488,025
Total Liabilities and Stockholders' Equity	\$ 81,229,412	\$ 68,113,629

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,	
	2007	2006	2007	2006
Product revenue	\$ 7,283,129	\$ 5,494,407	\$ 18,989,133	\$ 18,875,724
Licensing, milestone and contract revenue	682,251	706,250	2,213,855	2,075,934
Total revenue	7,965,380	6,200,657	21,202,988	20,951,658
Operating expenses:				
Cost of product revenue	3,138,307	2,125,028	8,655,010	8,063,750
Research & development	1,125,826	905,289	2,969,218	3,111,958
Selling, general & administrative	1,820,998	1,453,393	5,112,147	5,218,992
Total operating expenses	6,085,131	4,483,710	16,736,375	16,394,700
Income from operations	1,880,249	1,716,947	4,466,613	4,556,958
Interest income, net	550,014	569,229	1,692,622	1,520,075
Income before income taxes	2,430,263	2,286,176	6,159,235	6,077,033
Provision for income taxes	634,033	961,536	1,797,377	2,519,579
Net income	\$ 1,796,230	\$ 1,324,640	\$ 4,361,858	\$ 3,557,454
Basic net income per share:				
Net income	\$ 0.16	\$ 0.12	\$ 0.40	\$ 0.34
Basic weighted average common shares outstanding	11,152,686	10,676,943	11,018,208	10,602,659
Diluted net income per share:				
Net income	\$ 0.16	\$ 0.12	\$ 0.38	\$ 0.32
Diluted weighted average common shares outstanding	11,568,074	11,130,225	11,438,673	11,100,985

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

Anika Therapeutics, Inc. and Subsidiary

Consolidated Statements of Cash Flows

For the Nine Months Ended

(unaudited)

	September 30, 2007	September 30, 2006
Cash flows from operating activities:		
Net income	\$ 4,361,858	\$ 3,557,454
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation	519,064	293,760
Amortization of premium on short-term investment	17,993	
Stock-based compensation expense	638,756	1,071,747
Tax benefit related to exercise of stock option	(399,197)	(472,431)
Deferred income taxes	(228,377)	(173,172)
Provision for inventory reserve	91,579	
Changes in operating assets and liabilities:		
Accounts receivable	(1,456,438)	(681,681)
Inventories	591,386	(2,333,062)
Prepaid expenses, other current and long-term other assets	(446,765)	837,435
Accounts payable	458,570	(492,606)
Accrued expenses	90,661	32,149
Deferred revenue	1,410,006	(1,083,797)
Income taxes payable	765,280	1,795,693
Other long-term liabilities	203,718	63,410
Net cash provided by operating activities	6,618,094	2,414,899
Cash flows from investing activities:		
Purchase of short-term investment	(3,526,985)	
Purchase of property and equipment	(6,233,185)	(1,163,045)
Net cash used in investing activities	(9,760,170)	(1,163,045)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,645,261	949,509
Tax benefit from exercise of stock options	489,021	472,431
Net cash provided by financing activities	2,134,282	1,421,940
Increase (decrease) in cash and cash equivalents	(1,007,794)	2,673,794
Cash and cash equivalents at beginning of year	47,167,432	44,746,656
Cash and cash equivalents at end of period	\$ 46,159,638	\$ 47,420,450
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 1,164,000	\$ 533,719

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, repair and aesthetic enhancement. 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; HYVIS®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT®, which is an HA based anti-adhesive for surgical applications. In the U.S., ORTHOVISC® is marketed by DePuy Mitek, Inc., 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 15 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC®-II, which is distributed by STAAR Surgical Company and ShellGel® for Cytosol Ophthalmics, Inc. HYVIS® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. ELEVESS® is a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. ELEVESS® is approved in the U.S., EU and Canada, and is manufactured by Anika. Products in development include next generation ELEVESS®, and osteoarthritis / joint health related products. INCERT® is currently marketed in three countries outside of the U.S.

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 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 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, 2007, the results of its operations for the three and nine months ended September 30, 2007 and 2006 and its cash flows for the nine months ended September 30, 2007 and 2006.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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, 2006. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. The results of operations for the three and nine months ended September 30,

2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 or any future periods.

3. Summary of Significant Accounting Policies

Use of Estimates

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

Principles of Consolidation

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

Cash, Cash Equivalents and Short-term Investments

Cash and cash equivalents consists of cash and highly liquid investments with original maturities of 90 days or less. The Company accounts for short-term investments in accordance with 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.

Financial Instruments

SFAS No. 107, Disclosures About Fair Value of Financial Instruments, requires disclosure about fair value of financial instruments. Financial instruments consist of cash equivalents, investments, accounts receivable, and accounts payable. The estimated fair value of the Company's financial instruments approximate their carrying values.

Revenue Recognition

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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

Product Revenue

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

License, Milestone and Contract Revenue

On June 30, 2006, the Company entered into a License and Development Agreement with Galderma Pharma S.A., a joint venture between Nestlé and L'Oréal, and a Supply Agreement with Galderma Pharma S.A. and Galderma S.A., an affiliate of Galderma Pharma S.A., for the exclusive worldwide development and commercialization of hyaluronic acid based products used in aesthetic dermatology, formerly referenced as cosmetic tissue augmentation. Galderma Pharma S.A. and Galderma S.A. are hereinafter jointly referred to as Galderma. Under the agreements, the Company is responsible for the development and manufacturing of aesthetic dermatology products, and Galderma is responsible for the commercialization, including distribution and marketing, of aesthetic dermatology products worldwide. The agreements include an upfront payment, milestones upon achievement of predefined regulatory goals, funding of certain ongoing development activities, payments for the supply of aesthetic dermatology products, royalties on sales and sales threshold achievement payments for meeting certain net sales targets. The Company accounts for the agreements in accordance with the Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). Under the terms of the agreements, the Company received on June 30, 2006 a non-refundable, upfront payment of \$1,000,000, which the Company recognizes as revenue over the contractual 10 year term. Milestone payments under the agreements include payments related to regulatory approvals of aesthetic dermatology products in the United States and Europe. As of September 30, 2007, the Company has received \$3,500,000 of milestone payments related to the CE Marking and FDA approvals. This amount was recorded as deferred revenue. On November 5, 2007, the Company announced that it was in negotiations to terminate its License and Development Agreement and Supply Agreement with Galderma Pharma and Galderma S.A. Please refer to Note 10 for additional disclosures.

Accounts Receivable and Allowance for Doubtful Accounts

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

Stock-Based Compensation

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

Disclosures About Segments of an Enterprise and Related Information

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-

making group, in making decisions regarding how to allocate resources and assess performance. The Company's chief operating decision maker is its Chief Executive Officer. Based on the criteria established by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, the Company has one 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,	
	2007	2006	2007	2006
Ophthalmic Products	\$ 2,893,906	\$ 2,950,270	\$ 8,068,611	\$ 8,432,608
ORTHOVISC®	3,596,395	2,140,017	8,894,752	9,118,536
HYVISC®	552,773	388,580	1,682,870	1,298,540
Other	240,055	15,540	342,900	26,040
	\$ 7,283,129	\$ 5,494,407	\$ 18,989,133	\$ 18,875,724

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

	Percent of Product Revenue Three Months Ended September 30,		Percent of Product Revenue Nine Months Ended September 30,	
	2007	2006	2007	2006
Bausch & Lomb Incorporated	36.5%	48.9%	38.6%	40.8%
Depuy Mitek	34.3%	27.2%	35.7%	19.0%
Pharmaren AG / Biomeks	7.0%	4.4%	3.9%	21.2%
Boehringer Ingelheim Vetmedica	7.6%	7.1%	8.9%	6.9%
	85.4%	87.6%	87.1%	87.9%

As of September 30, 2007, seven customers represented 97% of the Company's accounts receivable balance and as of December 31, 2006, five customers represented 89% of the Company's accounts receivable balance.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Product revenue by geographic location in total and as a percentage of total product revenues are as follows:

	2007		Three Months Ended September 30,		2006	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:						
United States	\$ 5,057,754	69.5%	\$ 3,984,090	72.5%		
Turkey	520,278	7.1%	239,733	4.4%		
Europe and Other	1,705,097	23.4%	1,270,584	23.1%		
Total	\$ 7,283,129	100.0%	\$ 5,494,407	100.0%		

	2007		Nine Months Ended September 30,		2006	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue	Revenue	Percent of Revenue
Geographic location:						
United States	\$ 14,176,658	74.6%	\$ 11,134,562	59.0%		
Turkey	753,213	4.0%	3,998,226	21.2%		
Europe and Other	4,059,262	21.4%	3,742,936	19.8%		
Total	\$ 18,989,133	100.0%	\$ 18,875,724	100.0%		

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 which is effective for fiscal years beginning after November 15, 2007. This statement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. This statement will be effective for the Company beginning January 1, 2008. We are currently evaluating the potential impact of this statement.

4. Short-term Investment

In February 2007, the Company purchased a tax exempt municipal bond with a par value of \$3,500,000 and an interest rate of 4.25% maturing February 1, 2008 for a cost of \$3,526,985. The Company classifies its investments in debt and equity securities into held-to-maturity, available-for-sale or trading categories in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 115, Accounting For Certain Investments in Debt and Equity Securities. The tax exempt municipal bond is classified as held-to-maturity because the Company intends, and has the ability, to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. As of September 30, 2007, the amortized cost of the municipal bond is \$3,508,992.

5. Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, which established accounting for equity instruments exchanged for employee services. 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. 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 option term, the expected volatility of the Company's stock over the option's expected term, the risk-free interest rate over the option's expected term, and the Company's expected annual dividend yield. The Company uses historical data on exercise of stock options and other factors to estimate the expected term of share-based awards. The 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 grant. The fair value of each stock option and stock appreciation rights award during the three and nine months ended September 30, 2007 and 2006 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	September 30, 2007	September 30, 2006
Risk-free interest rate	4.12%	4.87%
Expected volatility	56.67%	65.56%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

	Nine Months Ended	
	September 30, 2007	September 30, 2006
Risk-free interest rate	4.12 - 4.80%	4.32 - 5.03%
Expected volatility	56.67 - 64.11%	65.56 - 65.82%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

The Company recorded \$151,877 and \$638,756 of share-based compensation expense for the three and nine months ended September 30, 2007, respectively, for stock options, stock appreciation rights and restricted stock awards. The Company recorded \$338,721 and \$1,071,747 of share based compensation expense for the three and nine months ended September 30, 2006, respectively, for stock options, stock appreciation rights and restricted stock awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the same employees. In the first quarter of 2007, the Company granted 10,000 shares of share-based stock appreciation rights and 200 shares of restricted stock to non-officer employees. The Company granted 20,000 shares of share-based stock appreciation rights to its employees during the second and third quarters of 2007 under the Stock Option and Incentive Plan. Total tax benefits realized from stock

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

option exercises were \$271,699 and \$301,705 for the three months ended September 30, 2007 and 2006, respectively. Total tax benefits realized from stock option exercises were \$652,521 and \$491,111 for the nine months ended September 30, 2007 and 2006, respectively. The Company received \$1,645,261 and \$949,509 for exercises of stock options during the nine months ended September, 2007 and 2006, respectively.

Stock-based awards activity for the nine months ended September 30, 2007 is summarized as follows:

	Stock Options and Stock Appreciation Rights Nine Months Ended September 30, 2007		Restricted Stock Nine Months Ended September 30, 2007	
	Number of Shares	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	1,547,412	\$ 6.39	23,900	\$ 11.80
Granted	30,000	\$ 15.63	200	\$ 13.09
Cancelled	(134,526)	\$ 10.83	(925)	\$ 11.91
Expired	(3,045)	\$ 12.11		
Exercised / Issued	(397,674)	\$ 4.17	(1,800)	\$ 10.51
Outstanding at end of period	1,042,167	\$ 6.92	21,375	\$ 11.92
Options exercisable at end of period	746,217	\$ 5.17		

6. Earnings Per Share

The Company reports earnings per share in accordance with SFAS No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of common shares outstanding and the number of dilutive potential common share equivalents during the period. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Weighted average number of shares of common stock	11,152,686	10,676,943	11,018,208	10,602,659
Dilutive stock options	415,388	453,282	420,465	498,326
Shares used in calculating diluted earnings per share	11,568,074	11,130,225	11,438,673	11,110,985

Options to purchase 10,000 and 110,000 shares were outstanding at the three and nine months ended September 30, 2007, respectively, but not included in the computation of diluted earnings per share because the effect is anti-dilutive. Options to purchase 36,187 and 146,937 shares were excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2006, respectively.

7. Inventories

Inventories consist of the following:

	September 30, 2007	December 31, 2006
Raw materials	\$ 3,219,390	\$ 2,935,075
Work-in-process	1,410,153	2,132,665
Finished goods	83,088	327,856
Total	\$ 4,712,631	\$ 5,395,596

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

8. Guarantor Arrangements

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

9. Income Taxes

The Company recorded provision for taxes of \$634,033 and \$961,536 for the three months ended September 30, 2007 and 2006, respectively. Provision for taxes were \$1,797,377 and \$2,519,579 for the nine months ended September 30, 2007 and 2006, respectively. The effective tax rates were 26.1% and 42.1% for the three months ended September 30, 2007 and 2006, respectively. The effective tax rates were 29.2% and 41.5% for the nine months ended September 30, 2007 and 2006, respectively. The reduction in effective tax rate in 2007 is primarily due to a favorable impact of a state investment tax credit as a result of the new facility project, a domestic manufacturing deduction, an increase in state and federal research and development credits, and the tax benefits realized from disqualifying events related to incentive stock option exercises during the period. The Company records 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.

The Company adopted the provisions of FIN 48, Accounting for Uncertainty in Income Taxes, as of January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in financial statements under SFAS No. 109 and prescribes a comprehensive model for the recognition, measurement, and financial statement disclosure of uncertain tax positions. Unrecognized tax benefits are the differences between tax positions taken, or expected to be taken, in tax returns, and the benefits recognized for accounting purposes pursuant to FIN 48. As a result of adoption of FIN 48 there was no change to the tax reserve for unrecognized tax benefits. As such, there was no change to retained

earnings as of January 1, 2007. The tax reserve for uncertain tax positions as of January 1, 2007 was \$302,063.

During the first quarter of 2007, the Company concluded an IRS audit for U.S. federal income tax for all years through 2004 with a settlement in the amount of \$143,785, of which \$73,968 are timing differences. This settlement reduced the balance of tax reserves for uncertain tax positions to \$158,278. In accordance with the provisions of FIN 48, the reserve was reclassified to other long-term liabilities from income taxes payable because payment is not anticipated within one year of the balance sheet date. It is the Company's policy to classify accrued interest and penalties as part of the accrued FIN 48 liability and record the expense in the provision for income taxes. As of September 30, 2007, income tax related interest and penalties was immaterial. Our U.S. federal income tax returns for the years 2005 and 2006 remain subject to examination, and our state income tax returns for all years through 2006 remain subject to examination.

10. Subsequent Event

On November 5, 2007, the Company announced that it is in negotiations with Galderma Pharma to terminate its license and development, and supply agreements. The Company has experienced technical and business disagreements with Galderma Pharma regarding the development and commercialization of the ELEVESS family of products. The disagreements concern certain aspects of the formulation of the current and future products as well as some elements of the strategy for commercialization. Given these disagreements, the Company and Galderma Pharma have mutually agreed to work towards a termination of the agreements. The Company is working to accomplish the termination and reacquisition of worldwide rights and control of the future development and marketing of ELEVESS as quickly as possible.

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 intention to increase market share for ORTHOVISC® in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;

our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;

the timing, scope and rate of patient enrollment for clinical trials;

development of possible new products;

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

the timing of and/or receipt of FDA or other regulatory approvals and/or reimbursement approvals of new or potential products;

our intention to seek patent protection for our products and processes;

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 ophthalmic viscoelastic products and our expectations regarding revenue from ophthalmic products;

our expectation for increases in operating expenses, including research and development and selling, general and administrative expenses;

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

our ability and timing with respect to filling vacancies in management positions;

the rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy of such cash;

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

our ability to terminate the existing license and development, and supply agreements with Galderma on terms favorable to the Company, and in a timely fashion;

our expectations regarding the commercial launch of the ELEVESS product;

our ability to license ELEVESS to a new distribution partner, anticipated because of the expected termination of the existing license and development, and supply agreements with Galderma, on terms favorable to the Company, or our ability to market ELEVESS on our own;

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

our expectations regarding regular order flow for ORTHOVISC; and international sales trend of ORTHOVISC;

our expectations regarding the result of the reimbursement change in Turkey and related ORTHOVISC sales in Turkey;

our expectations regarding sales to DePuy Mitek and the positive effects on domestic ORTHOVISC sales related to DePuy Mitek's expansion of its product specialist team, and our expectations of the simplified reimbursement process on ORTHOVISC sales;

our expectations regarding HYVISC sales;

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

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

our expectations regarding the terms of any future equity or debt financings.

Furthermore, additional statements identified by words such as will, likely, may, believe, expect, anticipate, intend, seek, designed, develop, would, future, can, could, outlook and other expressions that are predictions of or indicate future events and trends and which do not relate to historical matters, also identify forward-looking statements. You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled Item 1A Risk Factors in the Company's Annual Report on Form 10-K and in the section titled item 1A Risk Factors on page 25 of this Quarterly Report on Form 10-Q. 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 Discussion and Analysis of Financial Condition and Results of Operations beginning on page 14 of this Quarterly Report on Form 10-Q, as well as the risk

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

factors described in our Annual Report on Form 10-K for the year ended December 31, 2006 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to update or revise any forward-looking statement to reflect changes in underlying assumptions or factors of new information, future events or other changes.

Management Overview

Anika Therapeutics, Inc. (Anika, the Company, we, us or our) was incorporated in 1992 as a Massachusetts company. Anika develops, manufactures and commercializes therapeutic products for tissue protection, healing, repair and aesthetic enhancement. 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; HYVIS[®], which is an HA product used in the treatment of equine osteoarthritis, and INCERT[®], an HA based anti-adhesive for surgical applications. In the U.S., ORTHOVISC is marketed by DePuy Mitek, Inc., 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 15 countries. We developed and manufacture AMVISC[®] and AMVISC[®] Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC -II, which is distributed by STAAR Surgical Company and Shellgel for Cytosol Ophthalmics, Inc. HYVIS is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. ELEVESS is a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. ELEVESS is approved in the U.S., EU and Canada, and is manufactured by Anika. INCERT[®] is currently marketed in three countries outside of the U.S. Products in development include next generation ELEVESS , and osteoarthritis / joint health related products.

Osteoarthritis Business

We have marketed ORTHOVISC, our product for the treatment of osteoarthritis of the knee, internationally since 1996 through various distribution agreements. International sales of ORTHOVISC contributed 15.1% and 11.2% of product revenue, respectively, for the three and nine months ended September 30, 2007. International sales of ORTHOVISC increased 70.3% and decreased 61.6% for the three and nine month periods in 2007 compared to the same periods of 2006. International ORTHOVISC sales to Turkey, Canada, Austria and Germany increased during the third quarter of 2007 compared to the same period last year. The fluctuation in international ORTHOVISC sales for the three and nine month periods was primarily caused by lack of shipments to Turkey from August of 2006 to May of 2007, and increasing shipments in the second and third quarters of 2007. This was the result of a change in the government's reimbursement policy for over 100 drugs including ORTHOVISC and its competing products. Our shipments to Turkey resumed in the second quarter of 2007, and we expect to continue shipments to Turkey for the remainder of 2007. For 2007, we expect international sales to be lower compared to 2006 due to the reimbursement change in Turkey. During the third quarter of 2007, we continued discussions with potential distributors in China, Russia, Lebanon and several other countries in Eastern Europe and in Latin America. In addition, we have product registrations in process for ORTHOVISC in India, Saudi Arabia, Mexico, Chile and Brazil. Our partners will be seeking regulatory clearance for ORTHOVISC in a majority of these markets in order to begin selling product in 2008. We continue to seek new distribution partnerships around the world.

ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is currently marketed by JNJ, under the terms of a ten-year licensing, distribution, supply and marketing agreement (the JNJ Agreement). The JNJ Agreement was originally entered into with Ortho Biotech Products, L.P. (OBP), also a Johnson & Johnson company, and was assigned to DePuy Mitek in mid-2005. Revenue from ORTHOVISC in the U.S. contributed 34.3% and 35.7%, respectively, of our product revenue for the three and nine months ended September 30, 2007 and increased 67.1% and 88.6% from the same three and nine month periods of 2006. The significant increase in U.S. sales is partially due to DePuy Mitek's ability to leverage the separate reimbursement code granted in December 2006 along with the addition of sales specialists. These improvements have led to an increase in underlying sales to end-users which, combined with an increase in unit sales to DePuy Mitek for the three and nine months ended September 30, 2007 compared to the same periods of 2006, were the primary reason for the increases in U.S. sales. In December 2006, the Centers for Medicare and Medicaid Services assigned a unique reimbursement code to our ORTHOVISC product, effective January 1, 2007. This move has simplified the current reimbursement process and improved access to ORTHOVISC. The assignment of a reimbursement code removes a barrier to physician utilization of the product for

Medicare and Medicaid patients. We expect this change to have a positive impact on our U.S. ORTHOVISC sales throughout 2007.

Sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 7.6% and 8.9%, respectively, for the three and nine months ended September 30, 2007 and increased by 42.3% and 29.6% from the same three and nine month periods in 2006. Based on existing orders, we expect an increase in HYVISC sales for full year 2007. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the three and nine months ended September 30, 2007, sales of ophthalmic products contributed 39.7% and 42.5%, respectively, of our product revenue. Ophthalmic sales decreased by 1.9% and 4.3% compared to the three and nine month periods of 2006. Sales to Bausch & Lomb accounted for 91.9% and 90.9%, respectively, of ophthalmic sales for the three and nine months ended September 30, 2007. Sales to Bausch & Lomb accounted for 36.5% and 38.6%, respectively, of total product sales for the three and nine months ended September 30, 2007. We expect ophthalmic product sales for full year 2007 to be lower than the sales level in 2006.

Aesthetic Dermatology Business

ELEVESS, is a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our aesthetic dermatology product is a dermal filler based on a family of chemically modified, cross-linked forms of HA designed for longer duration in the body. We received European and United States FDA approvals for our initial product in April and July of 2007, respectively.

On June 30, 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Galderma Pharma for the exclusive worldwide development and commercialization of hyaluronic acid based aesthetic dermatology products. We experienced technical and business disagreements with Galderma Pharma regarding the development and commercialization of the ELEVESS family of products. The disagreements concern certain aspects of the formulation of the current and future products as well as some elements of the strategy for commercialization. On November 5, 2007, we announced that we are in negotiations with Galderma Pharma to terminate our license and development, and supply agreements. We are currently working with Galderma Pharma to complete the termination agreement and reacquisition of worldwide rights and control of the future development and marketing of ELEVESS as quickly as possible. We have received positive feedback from physicians and patients exposed to ELEVESS and believe that the product is ready for market. Once the existing agreements are terminated, we currently intend to proceed expeditiously towards commercialization. With a technologically enhanced product that is approved in the U.S., European Union and Canada, we expect to launch the product as soon as possible with a new partner, or initially on our own.

Anti-adhesion Business

INCERT® is an HA based anti-adhesive for surgical applications. CE marking approval for commercial marketing and sale was received in the third quarter of 2004. Sales of INCERT were \$17,835 and \$118,680 for the three and nine months ended September 30, 2007.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

We commenced INCERT sales during the second quarter of 2006 with limited distribution. We continue to assess the market potential for the product. There are currently no plans to distribute INCERT in the U. S.

Research and Development

Products in development include next generation osteoarthritis / joint health related products. Our next generation osteoarthritis products include a single-injection treatment product which is our first osteoarthritis product with a new HA- technology that uses a non-animal source material. This product has been branded as Monovisc . We received CE Mark approval for the Monovisc product in October 2007. We expect to launch Monovisc in Europe in the first quarter of 2008, following a limited clinical study. In the U.S. we have recently filed an investigational device exemption, or an IDE application, with the FDA and expect to begin clinical trial patient enrollment shortly.

Our second single-injection osteoarthritis product contains an active therapeutic molecule to provide broader pain relief for a longer period of time. This product has been branded Cingal . We are on track to receive CE Mark approval and commence a European commercial launch for this product in 2008. We expect to begin the U.S. pivotal clinical trial at about the same time.

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 in the Notes to the Consolidated Financial Statements of this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2007 and our Annual Report on Form 10-K for the year ended December 31, 2006.

Revenue Recognition.

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

Reserve for Obsolete/Excess Inventory.

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

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

Stock-based Compensation.

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, (SFAS 123R) Share-Based Payment, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant).

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

Deferred taxes.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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, 2007, 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.

Results of Operations**Three and nine months ended September 30, 2007 compared to three and nine months ended September 30, 2006.**

Product revenue. Product revenue for the quarter ended September 30, 2007 was \$7,283,129, an increase of \$1,788,722 or 32.6%, compared to \$5,494,407 for the quarter ended September 30, 2006. Product revenue for the nine months ended September 30, 2007 was \$18,989,133, an increase of \$113,409 or 0.6%, compared to \$18,875,724 for the nine months ended September 30, 2006.

Three Months Ended September 30,

(in thousands)

	2007		2006		Increase (Decrease)		
					\$	%	
Ophthalmic Products	\$	2,893,906	\$	2,950,270	\$	(56,364)	-1.9%
ORTHOVISC®		3,596,395		2,140,017		1,456,378	68.1%
HYVISC®		552,773		388,580		164,193	42.3%
Other		240,055		15,540		224,515	1444.8%
	\$	7,283,129	\$	5,494,407	\$	1,788,722	32.6%

Nine Months Ended September 30,

(in thousands)

	2007		2006		Increase (Decrease)		
					\$	%	
Ophthalmic Products	\$	8,068,611	\$	8,432,608	\$	(363,997)	-4.3%
ORTHOVISC®		8,894,752		9,118,536		(223,784)	-2.5%
HYVISC®		1,682,870		1,298,540		384,330	29.6%
Other		342,900		26,040		316,860	1216.8%
	\$	18,989,133	\$	18,875,724	\$	113,409	0.6%

The decrease in ophthalmic product sales for the three and nine months ended September 30, 2007 was primarily related to timing of Bausch & Lomb's orders, as there was an extra order in the first quarter of 2006 to replenish inventory levels. We anticipate a normal order pattern for 2007 and expect sales for the full year 2007 to be lower than the level in 2006.

ORTHOVISC sales increased for the three months and decreased for the nine months ended September 30, 2007 compared to the same periods in 2006. International sales of ORTHOVISC increased by 70.3% and decreased by 61.6% from the three and nine month periods last year. Increase in international sales of ORTHOVISC during the third quarter was due to increased shipments to Turkey, Canada, Austria and

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Germany. Fluctuations in international ORTHOVISC sales for the three and nine month periods was primarily due to the Turkish government's reimbursement policy change in the third quarter of 2006 for over 100 drugs, including ORTHOVISC and its competing products. As a result of the policy change, there was no shipment to Turkey from August of 2006 to May of 2007. Sales to Turkey were \$511,998 and \$732,603 for three and nine months ended September 30, 2007, respectively, compared to \$239,733 and \$3,998,226 for the comparable periods in 2006. We expect modest sales to Turkey during the fourth quarter of 2007, and international sales to decline moderately in 2007 compared to 2006 due to the reimbursement change in Turkey. Partially offsetting the

significant international ORTHOVISC sales decrease was an increase in revenue from our U.S. distributor, DePuy Mitek, which accounted for 34.3% and 35.7% of product revenue for the three and nine months ended September 30, 2007. Revenue from DePuy Mitek increased 67.1% and 88.6% from the three and nine month periods in 2006. DePuy Mitek's underlying sales to end-users increased in the three and nine month periods of 2007 compared to the same periods in 2006, which combined with an increase in unit sales to DePuy Mitek for the same period, were the primary reasons for the increase in U.S. sales. We expect domestic ORTHOVISC sales to increase from 2006 as DePuy Mitek continues to leverage the separate reimbursement code granted in December 2006.

HYVISC sales increased 42.3% and 29.6% for the three and nine month periods ended September 30, 2007 compared to the same periods last year. HYVISC sales contributed 7.6% and 8.9% of product revenue for the three and nine months ended September 30, 2007, respectively. We expect sales of HYVISC to increase in 2007 from 2006 based on current customer orders.

Other product revenue includes sales of ELEVESS and Incert. Sales of ELEVESS to Galderma Pharma were sample units, and were \$222,220 and \$224,220 for the three and nine months ended September 30, 2007. ELEVESS sales were paid in full by Galderma Pharma and are non-refundable. We do not expect additional sales to Galderma in the future due to the expected termination of the existing license and development, and supply agreements.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the three and nine months ended September 30, 2007 were \$682,251 and \$2,213,855, respectively, compared to \$706,250 and \$2,075,934, for the same periods last year. In 2007 licensing and milestone revenue includes the ratable recognition of the \$28,000,000 in non-refundable up-front and milestone payments related to agreements with JNJ and Galderma. These amounts are being recognized in income ratably over the ten-year expected life of the agreements, or \$700,000 per quarter.

Product gross profit. Product gross profit for the quarter ended September 30, 2007 was \$4,144,822, or 56.9% of product revenue, an increase of \$775,443, or 23.0%, from gross profit of \$3,369,379 representing 61.3% of product revenue, for the quarter ended September 30, 2006. For the nine months ended September 30, 2007, product gross profit was \$10,334,123, or 54.4% of product revenue, a decrease of \$477,851, or 4.4%, from gross profit of \$10,811,974 representing 57.3% of product revenue, for the nine months ended September 30, 2006. The decrease in product gross profit dollars was primarily due to product mix and timing of customer orders for the three and nine month periods in 2007 compared to 2006.

Research & development. Research and development expenses for the quarter ended September 30, 2007 was \$1,125,826, an increase of \$220,537, or 24.4%, compared to \$905,289 for the quarter ended September 30, 2006. For the nine months ended September 30, 2007, research and development expenses was \$2,969,218, a decrease of \$142,740, or 4.6%, compared to \$3,111,958 for the nine months ended September 30, 2006. Research and development expenses include costs associated with our development efforts for new products, the costs of animal and biocompatibility studies, clinical trials, manufacturing process improvements, and the preparation, filing and follow-up of applications for regulatory approvals at various relevant stages of development. For the first nine months of 2007, Research and development spending was focused on finalizing the long term follow-up of our European trial for our ELEVESS product, finalizing scale-up of ELEVESS manufacturing for commercial supply, as well as the development of second-generation osteoarthritis products. The increase in research and development expenses for the three months ended September 30, 2007 was primarily related to regulatory activities surrounding our second-generation osteoarthritis products and development activities related to ELEVESS manufacturing scale-up. The decrease in research and development expenses for the nine months ended September 30, 2007 was primarily attributable to modest spending on clinical trial expenses in the nine month period of 2007 compared to 2006. We expect increases in

research and development costs going forward related to the Company's next generation osteoarthritis products, ELEVESS line extensions and other research and development programs in the pipeline.

Selling, general & administrative. Selling, general and administrative expenses for the quarter ended September 30, 2007 was \$1,820,998, an increase of \$367,605, or 25.3%, compared to \$1,453,393 for the same period last year. For the nine months ended September 30, 2007, selling, general and administrative expenses was \$5,112,147, a decrease of \$106,845, or 2.0%, compared to \$5,218,992 for the same period last year. The increase in selling, general and administrative expenses for the three months ended September 30, 2007 was due primarily to rent and operating expenses at our new facility located in Bedford, Massachusetts, which is currently under construction. Our facility lease for the Bedford facility commenced in May of 2007. The decrease in selling, general and administrative expenses for the nine months ended September 30, 2007 was due primarily to higher legal costs in 2006 in connection with the Galderma agreements, along with higher consulting costs and stock compensation expense in 2006. The decreases were partially offset by the commencement of rent and operating expenses for the Company's new facility in Bedford. We expect that general and administrative expenses will increase due to costs related to the new facility as well as additional staffing.

Interest income, net. Net interest income for the three months ended September 30, 2007 was \$550,014, a decrease of \$19,215, or 3.4%, compared to \$569,229 for the same period last year. Net interest income for the nine months ended September 30, 2007 was \$1,692,622, an increase \$172,547 or 11.4%, compared to \$1,520,075 for the same period last year. The decrease for the three month period ended September 30, 2007 was due to lower interest rate as the company moved its money market investments to U.S. Treasury Bills as a result of the sub-prime mortgage crisis in the U.S. financial market. The increase in net interest income for the nine months ended September 30, 2007 was primarily attributable to higher available cash and invested balances. Interest income for the fourth quarter of 2007 is expected to decline as a result of lower expected available cash due to capital investments in the Company's new facility project.

Income taxes. Provision for income taxes was \$634,033 and \$961,536 related to income for the three months ended September 30, 2007 and 2006, respectively. The Company recorded a provision for income taxes of \$1,797,377 and \$2,519,579 for the nine months ended September 30, 2007 and 2006, respectively. The effective tax rate for the provision for the three and nine months ended September 30, 2007 were 26.1% and 29.2%, respectively. The effective tax rate for the provision for the three and nine months ended September 30, 2006 were 42.1% and 41.5%, respectively. The reduction in effective tax rate in 2007 is primarily due to a favorable impact of a state investment tax credit as a result of the new facility project, a domestic manufacturing deduction, an increase in state and federal research and development credits, and the tax benefits realized from disqualifying events related to incentive stock option exercises.

LIQUIDITY AND CAPITAL RESOURCES

We require cash to fund our operating expenses and capital expenditures. We expect that our requirement for cash to fund these uses will increase as the scope of our operations expand. Historically, we have funded our cash requirements from available cash and investments on hand. At September 30, 2007, cash, cash equivalents and short-term investments totaled \$49,668,630 compared to \$47,167,432 at December 31, 2006.

Cash provided by operating activities was \$6,618,094 for the nine months ended September 30, 2007 compared with \$2,414,899 for the nine months ended September 30, 2006. Cash provided by operating activities for the first nine months of 2007 increased by \$4,203,195 from the same period in 2006. The increase in cash from operating activities was primarily due to the receipt of \$3,500,000 milestone payments related to the Company's license and development agreement with Galderma.

Pharma. Increase in cash from operating activities was also caused by net income of \$4,361,858, net non-cash expenditures of \$639,818 and net cash provided by operating assets and liabilities of \$1,616,418.

Cash used in investing activities was \$9,760,170 for the nine months ended September 30, 2007, compared to \$1,163,045 for the nine months ended September 30, 2006. Cash used in investing activities for 2007 primarily reflects the February purchase of a short-term tax exempt municipal bond for \$3,526,985. The Company has also incurred approximately \$9,400,000 of capital expenditures as a result of the design, planning and build-out of the new facility project. Approximately \$3,500,000 of the \$9,400,000 was included in Accounts Payable and Accrued Expenses as of September 30, 2007. We expect to increase our capital expenditures in 2007 primarily related to the on going construction of our new facility. We expect the new facility capital project to cost approximately \$28 million (including interior construction, equipment, furniture and fixtures), of which approximately \$20 million will be spent or contractually committed during 2007. This new facility will serve as our corporate headquarters, research and development, and manufacturing facility for the foreseeable future. We plan to use a combination of cash on hand and debt to finance the build-out with up to approximately 60% provided by long-term debt. There can be no assurance that we will find available financing or financing on terms favorable to us. Construction at the new facility commenced in May of 2007 and will continue into 2008. There can also be no assurance that we will be successful in re-qualifying the new facility under the FDA and European Union regulations.

Cash provided by financing activities of \$2,134,282 and \$1,421,940 for the nine months ended September 30, 2007 and 2006, respectively, reflected the proceeds from exercises of stock options, including any associated tax benefits.

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* which is effective for fiscal years beginning after November 15, 2007. This statement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We are currently evaluating the potential impact of this statement.

Contractual Obligations

On January 4, 2007, the Company entered into a lease with Farley White Wiggins, LLC (FWW), as landlord, pursuant to which the Company will lease a new headquarters facility (the Lease), consisting of approximately 134,000 square feet of general office, research and development and manufacturing space located in Bedford, Massachusetts. Once occupancy is completed, it is anticipated that the new facility will provide the additional space necessary to accommodate growth in the Company's business, as well as to improve efficiency by conducting business in one facility.

The Lease commenced on May 1, 2007, upon the completion of certain improvements by the landlord, and has an initial term of ten and a half years. The Lease provides for an initial monthly base rent of \$26,042. The monthly base rent increases to \$46,875 on the first anniversary of the commencement date through July 31, 2010. On August 1, 2010, the monthly base rent increases to \$69,792 until the 6th anniversary of the commencement date upon which the monthly base rent will increase to \$80,958 until the end of the lease term. The Company has an option under the Lease to extend its terms for up to four periods beyond the original expiration date for a total of 21 additional years. The basic rent to be paid during any renewal term will be the greater of the fair market rent or the base rent for the lease year immediately preceding the commencement of the extension year.

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, 2006.

As of September 30, 2007, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107. Our investments consist of funds invested in U.S. Treasury Bills and a municipal bond 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. Our investment portfolio of cash equivalent and short-term investments is subject to interest rate fluctuations, but we believe this risk is immaterial due to the short-term nature of these investments.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

The Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in the Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Report required by Exchange Act Rules 13a-15(b) or 15d-15(b). The controls evaluation was conducted under the supervision and with the participation of the Company's management, including our chief executive officer and principal financial officer. Based on this evaluation, the chief executive officer and principal financial officer have concluded that as of the end of the period covered by this report the Company's disclosure controls and procedures were effective at a reasonable assurance level.

(b) Changes in internal controls.

There were no changes in our internal control over financial reporting during the third quarter of fiscal year 2007 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

PART II: OTHER INFORMATION

Item 1A. 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, 2006, 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. Except as disclosed below, there have been no material changes to the risk factors described in our Annual Report on Form 10-K, except to the extent previously updated or to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q related to such risk factors.

Termination of our license and supply agreements with Galderma Pharma could have a material adverse effect on us.

On November 5, 2007, we disclosed that we were in negotiations to terminate our License and Development Agreement (the License Agreement) with Galderma Pharma S.A and our Supply Agreement (together with the License Agreement, the Galderma Agreements) with Galderma Pharma S.A. and Galderma S.A. We entered into the Galderma Agreements on June 30, 2006 to provide for the exclusive worldwide development and commercialization of our hyaluronic acid based cosmetic tissue augmentation products, which we branded ELEVESS. Pursuant to the Galderma Agreements, Anika was to be responsible for the development and manufacturing of the ELEVESS products, and Galderma was to be responsible for the commercialization, including distribution and marketing, of the ELEVESS products worldwide. One of our objectives in seeking to terminate the Galderma Agreements is to reacquire worldwide rights and control of the future development and marketing of ELEVESS. Further, we are seeking a new distribution partner for the ELEVESS family of products. There can be no assurance that we will terminate the Galderma Agreements on terms favorable to us or that we will license ELEVESS to a new distribution partner on terms favorable to us, on terms that are as favorable to us as the Galderma Agreements or at all. If we are unable to terminate the Galderma Agreements on terms favorable to us or if we are unable to license ELEVESS on terms favorable to us or at all, such failures could have a material adverse effect on our future business, results of operations and financial condition.

Item 6. Exhibits

Exhibit No.

Description

(3) Articles of Incorporation and Bylaws

- | | |
|-----|--|
| 3.1 | The Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993. |
| 3.2 | Certificate of Vote of Directors Establishing a Series of Convertible Preferred Stock, incorporated herein by reference to Exhibits to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993. |

- 3.3 Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's quarterly report on Form 10-QSB for the period ended November 30, 1996, (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997.
- 3.4 Certificate of Vote of Directors Establishing a Series of a Class of Stock, incorporated herein by reference to Exhibit 3.1 of the Company's Registration Statement on Form 8-AB12 (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998.
- 3.5 Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.3 of the Company's quarterly report on Form 10-Q for the quarterly period ending June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002.
- 3.6 The Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.6 to the Company's quarterly report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002.

(4) Instruments Defining the Rights of Security Holders

- 4.1 Shareholder Rights Agreement dated as of April 6, 1998 between the Company and Firststar Trust Company, incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998.
- 4.2 Amendment to Shareholder Rights Agreement dated as of November 5, 2002 between the Company and American Stock Transfer and Trust Company, as successor to Firststar Trust Company incorporated herein by reference to Exhibit 4.2 to the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on November 13, 2002.

(11) Statement Regarding the Computation of Per Share Earnings

- *11.1 See Note 6 to the Financial Statements included herewith.

(31) Rule 13a-14(a)/15d-14(a) Certifications

- *31.1 Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- *31.2 Certification of Kevin W. Quinlan pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

(32) Section 1350 Certifications

- **32.1 Certification of Charles H. Sherwood, Ph.D. and Kevin W. Quinlan, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

ANIK THERAPEUTICS, INC.

November 9, 2007

By: /s/ Kevin W. Quinlan
Kevin W. Quinlan

Chief Financial Officer

(Principal Financial Officer)