ANIKA THERAPEUTICS INC
Form 10-Q
May 09, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2007

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

For the transition period from to

Commission File Number 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
160 New Boston Street, Woburn, Massachusetts	**01801**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: **(781) 932-6616**

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 last 90 days. Yes x No o

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

o Large accelerated filer x Accelerated filer o Non-accelerated filer

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the last practicable date. At May 8, 2007 there were 10,984,928 outstanding shares of Common Stock, par value $.01 per share.

PART I: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiary

Consolidated Balance Sheets

(unaudited)

	March 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,780,878	$ 47,167,432
Short-term investment	3,522,770	
Accounts receivable, net of reserves of $49,724 at March 31, 2007 and December 31, 2006	3,007,419	3,509,508
Inventories	5,983,632	5,395,596
Current portion deferred income taxes	1,312,901	1,312,901
Prepaid expenses and other receivables	469,051	220,445
Total current assets	58,076,651	57,605,882
Property and equipment, at cost	13,914,258	13,255,240
Less: accumulated depreciation	(10,398,890)	(10,237,232)
	3,515,368	3,018,008
Long-term deposits and other	399,300	193,050
Deferred income taxes	7,437,020	7,296,689
Total Assets	$ 69,428,339	$ 68,113,629
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,091,375	$ 965,180
Accrued expenses	1,115,208	1,573,835
Deferred revenue	2,899,969	2,905,099
Income taxes payable	145,946	17,253
Total current liabilities	5,252,498	5,461,367
Other long-term liabilities	223,939	64,525
Long-term deferred revenue	16,399,712	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 March 31, 2007 and December 31, 2006		
Common stock, $.01 par value; 30,000,000 shares authorized, 10,948,928 shares issued and outstanding at March 31, 2007, 10,772,654 shares issued and outstanding at December 31, 2006	109,489	107,727
Additional paid-in-capital	38,124,394	37,262,768
Retained earnings	9,318,307	8,117,530
Total stockholders equity	47,552,190	45,488,025
Total Liabilities and Stockholders Equity	$ 69,428,339	$ 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 March 31,	
	2007	**2006**
Product revenue	$ 5,374,038	$ 6,265,833
Licensing, milestone and contract revenue	764,008	687,127
Total revenue	6,138,046	6,952,960
Operating expenses:		
Cost of product revenue	2,492,922	3,047,818
Research & development	847,341	1,076,792
Selling, general & administrative	1,575,050	1,788,999
Total operating expenses	4,915,313	5,913,609
Income from operations	1,222,733	1,039,351
Interest income, net	566,777	461,074
Income before income taxes	1,789,510	1,500,425
Provision for income taxes	588,733	619,676
Net income	$ 1,200,777	$ 880,749
Basic net income per share:		
Net income	$ 0.11	$ 0.08
Basic weighted average common shares outstanding	10,878,448	10,526,672
Diluted net income per share:		
Net income	$ 0.11	$ 0.08
Diluted weighted average common shares outstanding	11,281,322	11,218,360

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

Anika Therapeutics, Inc. and Subsidiary

Consolidated Statements of Cash Flows

For the Three Months Ended

(Unaudited)

	March 31, 2007	March 31, 2006
Cash flows from operating activities:		
Net income	$ 1,200,777	$ 880,749
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	161,658	87,091
Stock-based compensation expense	277,321	382,537
Tax benefit related to exercise of stock option	(32,459)	(156,821)
Deferred income taxes	(140,331)	(67,945)
Provision for inventory reserve	63,362	
Changes in operating assets and liabilities:		
Accounts receivable	502,089	(174,137)
Inventories	(651,399)	(230,305)
Prepaid expenses	(248,606)	546,601
Long-term deposits and other	(206,250)	
Accounts payable	126,195	(488,447)
Accrued expenses	(458,627)	(517,959)
Deferred revenue	(705,130)	(737,185)
Income taxes payable	161,152	
Other long-term liabilities	159,414	
Net cash provided by (used in) operating activities	209,166	(475,821)
Cash flows from investing activities:		
Purchase of short-term investment	(3,522,770)	
Purchase of property and equipment	(659,018)	(366,257)
Net cash used in investing activities	(4,181,788)	(366,257)
Cash flows from financing activities:		
Proceeds from exercise of stock options	553,609	398,322
Tax benefit from exercise of stock options	32,459	156,821
Net cash provided by financing activities	586,068	555,143
Decrease in cash and cash equivalents	(3,386,554)	(286,935)
Cash and cash equivalents at beginning of year	47,167,432	44,746,656
Cash and cash equivalents at end of period	$ 43,780,878	$ 44,459,721
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 546,785	$ 7,532

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 currently marketed in three countries outside of the U.S. 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 20 countries. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. Products in development include ELEVESS™, an HA based dermal filler used for cosmetic dermatology applications and next generation osteoarthritis / joint health related products. In June 2006, we entered into a license and development agreement and a supply agreement with Galderma Pharma S.A. and Galderma S.A. for exclusive worldwide development and commercialization of cosmetic dermatology 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 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 March 31, 2007 and the results of its operations and its cash flows for the three months ended March 31, 2007 and 2006.

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. The results of operations for the three months ended March 31, 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, accounts receivable, and accounts payable. The estimated fair value of the Company s financial instruments approximate their carrying values.

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.

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 cosmetic dermatology (CD), 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 CD products, and Galderma is responsible for the commercialization, including distribution and marketing, of CD 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 CD 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 EITF 00-21, in order to account for an element as a separate unit of accounting, the element must have stand-alone value and there must be objective and reliable evidence of fair value of the undelivered elements. Based on the review of the agreements, the Company believes that two separate units of accounting exist: a combined license and development unit and a manufacturing and supply unit. Milestone payments related to achieving regulatory goals under the license and development unit are subject to certain refund

obligations, which are expected to expire by July 2007. Pursuant to this model, the Company will recognize payments received under the license and development unit upon expiration of refund contingencies, over the period in which the Company performs its obligations, which approximates the contractual term of 10 years. Using the contingency-adjusted performance model, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue. Payments from the manufacturing and supply unit will be recognized post commercialization as product is delivered.

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 will recognize as revenue over a 10 year period. Milestone payments under the agreements are related to regulatory approvals of CD products in the United States and Europe. Achievement of both regulatory approvals would entitle the Company to aggregate milestone payments of up to $5,000,000 for the initial CD product. The Company would also receive up to an additional $1,500,000 upon regulatory approvals in the United States and Europe for each additional CD product that the parties agree to develop and market. In addition, the agreements contain payment terms for supplying Galderma with CD products and royalties based on sales of the Company s CD products by Galderma to its customers. The agreements provide for sales threshold achievement payments of up to $14,500,000 if CD product net sales exceed certain net sales targets. Under the terms of the agreements, Galderma will support the development of the Company s CD products, including reimbursement for certain clinical development costs for line extensions and clinical trial support, and the Company will make appropriate regulatory filings with the U.S. Food and Drug Administration and regulators in the European Union to enhance features of its initial CD product. The agreements have an initial term of ten years, unless earlier terminated pursuant to any one of several early termination rights of each party. In certain circumstances, an early termination of the agreements will require the Company to refund to Galderma certain product development milestone payments and reimbursements of development costs. Following the initial term, the agreements will automatically renew for an additional three year period if a certain net sales target has been exceeded, unless terminated by Galderma prior to the expiration of the initial term.

Accounts Receivable and Allowance for Doubtful Accounts

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

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 March 31, 2007	2006
Ophthalmic Products	$ 2,285,121	$ 2,937,170
ORTHOVISC®	2,643,297	2,641,423
HYVISC®	428,925	687,240
INCERT®	16,695	
	$ 5,374,038	$ 6,265,833

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

	Percent of Product Revenue Three Months Ended March 31, 2007		2006	
Bausch & Lomb Incorporated	37.7	%	43.2	%
Pharmaren AG / Biomeks		%	21.8	%
Depuy Mitek / Ortho Biotech	40.9	%	13.5	%
Boehringer Ingelheim Vetmedica	8.0	%	11.0	%
	86.6	%	89.5	%

As of March, 31 2007, four customers represented 93% of the Company s accounts receivable balance and as of December 31, 2006, five customers represented 89% of the Company s accounts receivable balance.

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

	Three Months Ended March 31, 2007			2006		
	Revenue	Percent of Revenue		Revenue	Percent of Revenue	
Geographic location:						
United States	$ 4,217,681	78.5	%	$ 3,900,824	62.3	%
Turkey			%	1,367,188	21.8	%
Europe and Other	1,156,357	21.5	%	997,821	15.9	%
Total	$ 5,374,038	100.0	%	$ 6,265,833	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. 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 March 31, 2007, the amortized cost of the municipal bond is $3,522,770.

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5. Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions 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 first three months of 2007 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31, 2007	March 31, 2006
Risk-free interest rate	4.80%	4.32% 4.46%
Expected volatility	64.11%	65.76%
Expected lives (years)	4	4
Expected dividend yield	0.00%	0.00%

The Company recorded $277,321 and $382,537 of share-based compensation expense during the first quarter of 2007 and 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. These awards were granted under the Stock Option and Incentive Plan approved by the Board of Directors on April 4, 2003. See discussions under Stock Option Plans for more details, including key standard terms.

Stock Option Plans

The Company had reserved 3,485,000 shares of common stock for the grant of stock options to employees, directors, consultants and advisors under the Anika Therapeutics, Inc. 1993 Stock Option Plan, as amended (the 1993 Plan). In addition, the Company also established the Directors Stock Option Plan (the Directors Plan) and reserved 40,000 shares of the Company s common stock for issuance to the Board of Directors. On March 3, 2003, the 1993 Plan expired in accordance with its terms and approximately 662,000 shares reserved under the 1993 plan were released. On April 4, 2003 the Board of Directors approved the 2003 Anika Therapeutics, Inc. Stock Option and Incentive Plan (the 2003 Plan). The Company has reserved 1,500,000 shares of common stock for grant to employees, directors, consultants and advisors under the 2003 Plan, which was approved by stockholders on June 4, 2003. The Company issues new shares upon share option exercise from its authorized shares. Stock-based awards are granted with an exercise price equal to the market price of the Company s stock on the date of grant. Awards contain a service condition and generally vest over 4 years with 25% of the shares vesting on each of the four anniversary dates from the grant date. Awards have 10-year contractual terms.

Combined stock-based awards activity under the three plans is summarized as follows:

	Stock Options and Stock Appreciation Rights