

ANIKA THERAPEUTICS INC
Form 10-Q
August 07, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 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
(I.R.S. Employer Identification No.)

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

01801
(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 No

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):

Large accelerated filer Accelerated filer Non-accelerated filer

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

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Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the last practicable date. At July 25, 2007 there were 11,129,959 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)

	June 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,751,227	\$ 47,167,432
Short-term investment	3,515,949	
Accounts receivable, net of reserves of \$49,724 at June 30, 2007 and December 31, 2006	6,751,264	3,509,508
Inventories	5,537,691	5,395,596
Current portion deferred income taxes	1,312,901	1,312,901
Prepaid expenses and other receivables	427,665	220,445
Total current assets	62,296,697	57,605,882
Property and equipment, at cost	16,054,707	13,255,240
Less: accumulated depreciation	(10,573,883)	(10,237,232)
	5,480,824	3,018,008
Long-term deposits and other	399,300	193,050
Deferred income taxes	7,484,459	7,296,689
Total Assets	\$ 75,661,280	\$ 68,113,629
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,616,131	\$ 965,180
Accrued expenses	1,496,690	1,573,835
Deferred revenue	3,135,718	2,905,099
Income taxes payable	264,257	17,253
Total current liabilities	7,512,796	5,461,367
Other long-term liabilities	305,195	64,525
Long-term deferred revenue	17,499,712	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 June 30, 2007 and December 31, 2006		
Common stock, \$.01 par value; 30,000,000 shares authorized, 11,128,703 shares issued and outstanding at June 30, 2007, 10,772,654 shares issued and outstanding at December 31, 2006	111,287	107,727
Additional paid-in-capital	39,549,132	37,262,768
Retained earnings	10,683,158	8,117,530
Total stockholders' equity	50,343,577	45,488,025
Total Liabilities and Stockholders' Equity	\$ 75,661,280	\$ 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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Product revenue	\$ 6,331,966	\$ 7,115,484	\$ 11,706,004	\$ 13,381,318
Licensing, milestone and contract revenue	767,596	682,557	1,531,604	1,369,684
Total revenue	7,099,562	7,798,041	13,237,608	14,751,002
Operating expenses:				
Cost of product revenue	3,023,781	2,890,904	5,516,703	5,938,722
Research & development	996,051	1,129,877	1,843,392	2,206,669
Selling, general & administrative	1,716,099	1,976,600	3,291,149	3,765,599
Total operating expenses	5,735,931	5,997,381	10,651,244	11,910,990
Income from operations	1,363,631	1,800,660	2,586,364	2,840,012
Interest income, net	575,831	489,772	1,142,608	950,846
Income before income taxes	1,939,462	2,290,432	3,728,972	3,790,858
Provision for income taxes	574,611	938,367	1,163,344	1,558,043
Net income	\$ 1,364,851	\$ 1,352,065	\$ 2,565,628	\$ 2,232,815
Basic net income per share:				
Net income	\$ 0.12	\$ 0.13	\$ 0.23	\$ 0.21
Basic weighted average common shares outstanding	11,018,053	10,601,336	10,949,629	10,564,902
Diluted net income per share:				
Net income	\$ 0.12	\$ 0.12	\$ 0.23	\$ 0.20
Diluted weighted average common shares outstanding	11,376,673	10,955,156	11,342,280	10,969,569

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 Six Months Ended

(Unaudited)

	June 30, 2007	June 30, 2006
Cash flows from operating activities:		
Net income	\$ 2,565,628	\$ 2,232,815
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation	336,651	203,356
Amortization of premium on short-term investment	11,036	
Stock-based compensation expense	486,879	733,026
Tax benefit related to exercise of stock option	(331,198)	(183,272)
Deferred income taxes	(187,770)	(124,559)
Provision for inventory reserve	63,362	
Changes in operating assets and liabilities:		
Accounts receivable	(3,241,756)	(701,451)
Inventories	(205,457)	(1,164,414)
Prepaid expenses	(207,220)	567,012
Long-term deposits and other	(206,250)	
Accounts payable	1,650,951	(235,557)
Accrued expenses	(77,145)	(73,229)
Deferred revenue	630,619	(389,622)
Income taxes payable	578,202	757,785
Other long-term liabilities	240,670	
Net cash provided by operating activities	2,107,202	1,621,890
Cash flows from investing activities:		
Purchase of short-term investment	(3,526,985)	
Purchase of property and equipment	(2,799,467)	(1,032,056)
Net cash used in investing activities	(6,326,452)	(1,032,056)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,471,847	607,292
Tax benefit from exercise of stock options	331,198	183,272
Net cash provided by financing activities	1,803,045	790,564
Increase (decrease) in cash and cash equivalents	(2,416,205)	1,380,398
Cash and cash equivalents at beginning of year	47,167,432	44,746,656
Cash and cash equivalents at end of period	\$ 44,751,227	\$ 46,127,054
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 608,000	\$ 261,477

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; HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, ELEVESSTM , which is a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, 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. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC™-II, which is distributed by STAAR Surgical Company and Shellgel™ for Cytosol Ophthalmics, Inc. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. ELEVESSTM will be marketed worldwide by Galderma Pharma. Products in development include next generation ELEVESSTM, and osteoarthritis / joint health related products.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with 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 June 30, 2007, the results of its operations for the three and six months ended June 30, 2007 and 2006 and its cash flows for the six months ended June 30, 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 and six months ended June 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

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 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 expired in 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 recognizes as revenue over a 10 year period. Milestone payments under the agreements are related to regulatory approvals of aesthetic dermatology 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 aesthetic dermatology product. The Company received the European and United States FDA approvals in April and July of 2007, respectively. The Company would also receive up to an additional \$1,500,000 upon regulatory approvals in the United States and Europe for each additional aesthetic dermatology product that the parties agree to develop and market. In addition, the agreements contain payment terms for supplying Galderma with aesthetic dermatology products and royalties based on sales of the Company's aesthetic dermatology products by Galderma to its customers. The agreements provide for sales threshold achievement payments of up to \$14,500,000 if product net sales exceed certain net sales targets. Under the terms of the agreements, Galderma will support the development of the Company's aesthetic dermatology 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 aesthetic dermatology 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. These contingencies expired on July 31, 2007. 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

Accounts receivable are recorded at the invoiced amount and do not bear interest. Included in the June 30, 2007 balance was an unbilled milestone receivable of \$2,000,000 due from Galderma related to the April 2007 CE Mark approval for the enhanced product, ELEVESS, with a twelve month shelf life. This receivable has been recorded as deferred revenue at June 30, 2007. 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.

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Product revenue by product group is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Ophthalmic Products	\$ 2,889,585	\$ 2,545,170	\$ 5,174,706	\$ 5,482,340
ORTHOVISC®	2,655,059	4,337,094	5,298,356	6,978,518
HYVISC®	701,172	222,720	1,130,097	909,960
Other	86,150	10,500	102,845	10,500
	\$ 6,331,966	\$ 7,115,484	\$ 11,706,004	\$ 13,381,318

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

	Percent of Product Revenue Three Months Ended June 30,		Percent of Product Revenue Six Months Ended June 30,	
	2007	2006	2007	2006
Bausch & Lomb Incorporated	41.8	% 32.4	% 39.9	% 37.5
Pharmaren AG / Biomeks	3.5	% 33.6	% 1.9	% 28.1
Depuy Mitek / Ortho Biotech	32.9	% 17.6	% 36.5	% 15.7
Boehringer Ingelheim Vetmedica	11.1	% 3.1	% 9.7	% 6.8
	89.3	% 86.7	% 88.0	% 88.1

As of June 30, 2007, six customers represented 98% 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 June 30, 2007	2006
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