

ANIKA THERAPEUTICS INC  
Form 10-Q  
August 07, 2006

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**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, 2006**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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

**04-3145961**  
(I.R.S. Employer Identification No.)

**01801**  
(Zip Code)

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

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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):

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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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the last practicable date.  
2006 there were 10,626,784 outstanding shares of Common Stock, par value \$.01 per share.

At July 24,

**PART I: FINANCIAL INFORMATION****ITEM 1: FINANCIAL STATEMENTS**

**Anika Therapeutics, Inc. and Subsidiary**  
**Consolidated Balance Sheets**  
(unaudited)

	June 30, 2006	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 46,127,054	\$ 44,746,656
Accounts receivable, net of reserves of \$49,724 at June 30, 2006 and \$22,558 at December 31, 2005	2,767,691	2,066,240
Inventories	4,435,092	3,270,678
Current portion deferred income taxes	1,301,085	1,301,085
Prepaid expenses and other receivable	458,469	1,025,481
Total current assets	55,089,391	52,410,140
Property and equipment, at cost	12,981,495	11,949,439
Less: accumulated depreciation	(10,056,533)	(9,853,177)
	2,924,962	2,096,262
Long-term deposits	143,060	143,060
Deferred income taxes	8,093,040	7,968,481
Total Assets	\$ 66,250,453	\$ 62,617,943
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,042,225	\$ 1,277,782
Accrued expenses	1,583,374	1,718,916
Deferred revenue	2,890,702	2,830,046
Income taxes payable	574,513	
Total current liabilities	6,090,814	5,826,744
Other long-term liabilities	62,313	
Long-term deferred revenue	18,449,722	18,900,000
Commitments and contingencies (note 7)		
Stockholders' equity		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at June 30, 2006 and December 31, 2005		
Common stock, \$.01 par value; 30,000,000 shares authorized, 10,625,584 shares issued and outstanding at June 30, 2006, 10,500,393 shares issued and outstanding at December 31, 2005	106,256	105,004
Additional paid-in-capital	35,795,219	34,272,881
Retained earnings	5,746,129	3,513,314
Total stockholders' equity	41,647,604	37,891,199
Total Liabilities and Stockholders' Equity	\$ 66,250,453	\$ 62,617,943

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,	
	2006	2005	2006	2005
Product revenue	\$ 7,115,484	\$ 4,084,132	\$ 13,381,318	\$ 9,761,069
Licensing, milestone and contract revenue	682,557	2,935,293	1,369,684	4,549,643
Total revenue	7,798,041	7,019,425	14,751,002	14,310,712
<b>Operating expenses:</b>				
Cost of product revenue	2,890,904	2,117,208	5,938,722	5,111,172
Research & development	1,129,877	1,460,170	2,206,669	2,659,379
Selling, general & administrative	1,976,600	1,475,164	3,765,599	2,767,239
Total operating expenses	5,997,381	5,052,542	11,910,990	10,537,790
Income from operations	1,800,660	1,966,883	2,840,012	3,772,922
Interest income	489,772	274,084	950,846	486,293
Income before income taxes	2,290,432	2,240,967	3,790,858	4,259,215
Provision for income taxes	938,367	904,478	1,558,043	1,720,486
Net income	\$ 1,352,065	\$ 1,336,489	\$ 2,232,815	\$ 2,538,729
<b>Basic net income per share:</b>				
Net income	\$ 0.13	\$ 0.13	\$ 0.21	\$ 0.25
Basic weighted average common shares outstanding	10,601,336	10,391,538	10,564,902	10,330,883
<b>Diluted net income per share:</b>				
Net income	\$ 0.12	\$ 0.12	\$ 0.20	\$ 0.22
Diluted weighted average common shares outstanding	10,955,156	11,537,538	10,969,569	11,425,292

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, 2006	June 30, 2005
<b>Cash flows from operating activities:</b>		
Net income	\$ 2,232,815	\$ 2,538,729
<b>Adjustments to reconcile net income to net cash from operating activities:</b>		
Depreciation	203,356	222,889
Stock-based compensation expense	733,026	
Tax benefits from exercises of stock options		1,105,436
Change in income taxes payable related to exercise of stock options	(183,272)	)
Deferred income taxes	(124,559)	)
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(701,451)	(390,032)
Inventories	(1,164,414)	) 190,104
Prepaid expenses and other receivable	567,012	722,838
Accounts payable	(235,557)	) (409,695)
Income taxes payable	757,785	
Accrued expenses and other long-term liabilities	(73,229)	) (583,290)
Deferred revenue	(389,622)	) (2,981,783)
Net cash provided by operating activities	1,621,890	415,196
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(1,032,056)	) (326,063)
Net cash used in investing activities	(1,032,056)	) (326,063)
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	607,292	502,042
Tax benefits from exercises of stock options	183,272	
Net cash provided by financing activities	790,564	502,042
Increase in cash and cash equivalents	1,380,398	591,175
Cash and cash equivalents at beginning of period	44,746,656	39,339,359
Cash and cash equivalents at end of period	\$ 46,127,054	\$ 39,930,534
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	\$ 261,477	\$ 25,113

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 and healing. 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; and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. 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 over 15 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. INCERT® is a HA based anti-adhesive for surgical applications. Potential products in development include an HA based dermal filler used for cosmetic tissue augmentation (CTA) applications. 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 CTA 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 June 30, 2006 and the results of its operations and its cash flows for the six months ended June 30, 2006 and 2005.

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, 2005. The results of operations for the three and six months ended June 30, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006 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 and Cash Equivalents*

Cash and cash equivalents consists of cash and highly liquid investments with original maturities of 90 days or less.

*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*.

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 CTA products. Galderma Pharma S.A. and Galderma S.A. are jointly referred to as Galderma. Under the agreements, the Company will be responsible for the development and manufacturing of the CTA products, and Galderma will be responsible for the commercialization, including distribution and marketing, of the CTA products worldwide. The agreements include an up front payment, milestones upon achievement of predefined regulatory goals, funding of ongoing development activities, payments for the supply of CTA products, royalties on sales and sales threshold achievement payments for meeting certain net sales targets. The Company will account 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 recorded as deferred revenue as of June 30, 2006.

Milestone payments under the agreements are related to final regulatory approvals of the CTA products in the United States and Europe. Achievements of regulatory approvals would entitle the Company to aggregate milestone payments of up to \$5,000,000 for the initial CTA product and up to an additional \$1,500,000 for each additional CTA product that the parties agree to develop and market. In addition, the agreements contain payment terms for supplying Galderma with CTA products and royalties based on sales of the Company's CTA products by Galderma to its customers. The agreements provide for sales threshold achievement payments of up to \$14,500,000 if CTA product net sales exceed certain net sales targets. Under the terms of the agreements, Galderma will support the development of the Company's CTA products, including reimbursement for certain development costs for the enhancement of the initial CTA product, 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 CTA 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 monthly. Past due balances over 90 days and over a specified amount 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. The Company elected to adopt the modified prospective transition method as provided by SFAS 123R and, accordingly, financial statement amounts for the prior periods presented in this Form 10-Q have not been restated to reflect the fair value method of expensing share-based compensation. See Note 4 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. Substantially 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		Six Months Ended	
	June 30, 2006	2005	June 30, 2006	2005
Ophthalmic Products	\$ 2,545,170	\$ 1,569,822	\$ 5,482,340	\$ 4,338,477
ORTHOVISC®	4,337,094	2,191,750	6,978,518	4,593,130
HYVISC®	222,720	322,560	909,960	829,462
INCERT®	10,500		10,500	
	\$ 7,115,484	\$ 4,084,132	\$ 13,381,318	\$ 9,761,069

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

	Percent of Product Revenue			Percent of Product Revenue		
	Three Months Ended June 30, 2006		2005	Six Months Ended June 30, 2006		2005
Bausch & Lomb Incorporated	32.4	%	29.8	% 37.5	%	38.1
Pharmaren AG/Biomexs	33.6	%	38.8	% 28.1	%	28.0
Depuy Mitek / Ortho Biotech	17.6	%	6.6	% 15.7	%	10.6
Boehringer Ingelheim Vetmedica	3.1	%	7.9	% 6.8	%	8.5
	86.7	%	83.1	% 88.1	%	85.2

As of June 30, 2006, five customers represented 92% of the Company's accounts receivable balance and as of December 31, 2005, six customers represented 91% 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:

Geographic location:	Three Months Ended June 30, 2006		2005	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	\$ 3,276,354	46.1 %	\$ 1,856,523	45.5 %
Turkey	2,391,305	33.6 %	1,586,012	38.8 %
Europe and Other	1,447,825	20.3 %	641,597	15.7 %
Total	\$ 7,115,484	100.0 %	\$ 4,084,132	100.0 %

Geographic location:	Six Months Ended June 30, 2006		2005	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	\$ 7,150,471	53.4 %	\$ 5,547,907	56.8 %
Turkey	3,758,493	28.1 %	2,732,858	28.0 %
Europe and Other	2,472,354	18.5 %	1,480,304	15.2 %
Total	\$ 13,381,318	100.0 %	\$ 9,761,069	100.0 %

#### Recent Accounting Pronouncements

In July 2006, the FASB issued FIN 48 Accounting for Uncertainty in Income Taxes. This interpretation requires that we recognize in our financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

In May 2005, the FASB, as part of an effort to conform to international accounting standards, issued SFAS No. 154, Accounting Changes and Error Corrections, (SFAS 154). SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 or beginning on July 1, 2006. SFAS 154 requires that all voluntary changes in accounting principles be retrospectively applied to prior financial statements as if that principle had always been used, unless it is impracticable to do so. When it is impracticable to calculate the effects on all prior periods, SFAS 154 requires that the new principle be applied to the earliest period practicable. SFAS 154 also redefines restatement as the revising of previously issued financial statements to reflect the correction of an error. The adoption of SFAS 154 did not have a material effect on our financial position or results of operations.

#### 4. Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions SFAS 123R, which establishes 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 grants. The fair value of each stock option and stock appreciation rights awards during the first six months of 2006 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:



	Three Months Ended		June 30, 2005	
	June 30, 2006			
Risk-free interest rate	5.03	%	3.66% - 3.8	5%
Expected volatility	65.82	%	69.02% - 69.1	7%
Expected lives (years)	4		4	
Expected dividend yield	0.00	%	0.00	%

	Six Months Ended		June 30, 2005	
	June 30, 2006			
Risk-free interest rate	4.32% - 5.03%		3.54% - 3.85%	
Expected volatility	65.77% - 65.82%		69.02% - 71.38%	
Expected lives (years)	4		4	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$350,490 and \$733,026 of share-based compensation expense during the three and six months ended June 30, 2006 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. Prior to 2006, the Company granted stock options to employees and members of the Board of Directors. In the first quarter of 2006, the Company granted 94,850 shares of share-based stock appreciation rights to members of its Board of Directors and company officers. The Company also granted 12,500 shares of stock options and 10,500 shares of restricted stock to non-officer employees during the first quarter of 2006. During the second quarter of 2006, the Company granted 5,000 shares of share-based stock appreciation rights to an employee. 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. The Company did not recognize compensation expense for employee share-based awards for the three and six months ended June 30, 2005, when the exercise price of the Company's employee stock awards equaled the market price of the underlying stock on the date of grant.

The Company had previously adopted the provisions of Statement of Financial Accounting Standards No. 123, [Accounting for Stock-Based Compensation](#), (SFAS 123), as amended by SFAS No. 148, [Accounting for Stock-Based Compensation Transition and Disclosure](#) through disclosure only. The following table illustrates the effects on net income and earnings per share for the three and six months ended June 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to share-based employee awards.

	Three Months Ended	Six Months Ended
	June 30, 2005	June 30, 2005
Net Income		
As reported	\$ 1,336,489	\$ 2,538,729
Add: Stock based employee compensation expense included in reported net income		
Deduct: Total stock-based employee compensation under the fair-value-based method for all awards, net of taxes	(184,123	) (329,780
Proforma net income	\$ 1,152,366	\$ 2,208,949
Basic net income per share		
As reported	0.13	0.25
Proforma net income	0.11	0.21
Diluted net income per share		
As reported	0.12	0.22
Proforma	0.10	0.19

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For the three and six months ended June 30, 2006, the adoption of SFAS 123R had the following effect on the Company's consolidated statements of operations:

	<b>Three Months Ended June 30, 2006</b>	<b>Six Months Ended June 30, 2006</b>
Cost of product revenue	\$ 72,247	\$ 142,140
Research & development	67,700	121,293
Selling, general & administrative	210,543	469,593
Income from operations	350,490	733,026
Income tax benefit	(82,981)	(310,098)
Net stock-based compensation expense	\$ 267,509	\$ 422,928
Basic net income per share	\$ 0.03	\$ 0.04
Diluted net income per share	\$ 0.02	\$ 0.04

**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 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 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:

	<b>Stock Options and Stock Appreciation Rights Six Months Ended June 30, 2006</b>		<b>Restricted Stock Six Months Ended June 30, 2006</b>	
	<b>Number of Shares</b>	<b>Weighted Average Exercise Price per Share</b>	<b>Number of Shares</b>	<b>Weighted Average Exercise Price per Share</b>
Outstanding at beginning of year	1,795,394	\$ 5.80		
Granted	112,350	\$ 10.52	10,500	\$ 10.51
Canceled	(70,002)	\$ 7.60	(2,100)	\$ 10.51
Exercised	(125,191)	\$ 4.85		
Outstanding at end of year	1,712,551	\$ 6.10	8,400	\$ 10.51
Shares exercisable at end of period	1,056,051	\$ 3.86		\$ 10.51

The aggregate intrinsic value of stock options and stock appreciation rights fully vested at June 30, 2006 was \$6,215,206. The aggregate intrinsic value of outstanding awards at June 30, 2006 was \$6,746,192. The total intrinsic value of options, stock appreciation rights and restricted stock units exercised was \$368,422 and \$846,500 for the three and six months ended June 30, 2006. Total tax benefits realized from stock option exercises were \$26,452 and \$966,567 for the three months ended June 30, 2006 and 2005, respectively. Total tax benefits realized from stock option exercises were \$183,272 and \$1,105,436 for the six months ended June 30, 2006 and 2005, respectively. The Company received \$208,968 and \$366,547 for exercises of stock options during the three months ended June 30, 2006 and 2005, respectively.

A summary of the activity for nonvested stock options and stock appreciation rights awards as of June 30, 2006 and changes during the six month period is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Nonvested at January 1, 2006	766,838	\$ 4.97
Granted	112,350	\$ 5.62
Vested	(154,275 )	\$ 2.67
Cancelled	(68,413 )	\$ 4.93
Nonvested at June 30, 2006	656,500	\$ 5.63

The following table summarizes significant ranges of outstanding stock options and stock appreciation rights under the three plans at June 30, 2006:

Range of Exercise Prices	Stock Options and Stock Appreciation Rights Outstanding			Shares Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$0.90 - \$1.05	325,513	6.00	\$ 1.01	286,951	5.93	\$ 1.01
\$1.06 - \$4.75	352,244	4.86	\$ 1.41	346,869	5.20	\$ 1.38
\$4.76 - \$9.21	363,688	5.18	\$ 7.21	248,312	3.60	\$ 6.50
\$9.22 - \$10.50	338,756	7.72	\$ 9.38	149,131	7.43	\$ 9.30
\$10.51 - \$15.45	332,350	9.24	\$ 11.50	24,788	8.91	\$ 12.47
	1,712,551	6.56	\$ 6.10	1,056,051	5.42	\$ 3.86

As of June 30, 2006, the weighted average fair value per share for options and stock appreciation rights for shares outstanding and vested were \$2.01 and \$1.55, respectively. As of June 30, 2006, there was approximately \$2.8 million, net of forfeiture assumptions, of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Company's stock plans. That cost is expected to be recognized over a weighted average period of 2.58 years.

## 5. 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, assumed proceeds is the sum of (i) unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later; (ii) the amount of compensation cost attributed to future services and not yet recognized; and (iii) the amount of tax benefits that would be credited to additional paid-in capital assuming exercise of the stock-based compensation. 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 six-month ended June 30, are as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2006	2005	June 30, 2006	2005
Weighted average number of shares of common stock outstanding	10,601,336	10,391,538	10,564,902	10,330,883
Dilutive stock options	353,820	1,146,000	404,667	1,094,409
Shares used in calculating diluted earnings per share	10,955,156	11,537,538	10,969,569	11,425,292

Options to purchase 237,000 and 157,000 shares were outstanding at the three and six months ended June 30, 2006, respectively, but not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price during the period. Options to purchase 10,125 and 36,625 shares were excluded from the computation of diluted earnings per share for the three and six months ended June 30, 2005, respectively.

## 6. Inventories

Inventories consist of the following:

	June 30, 2006	December 31, 2005
Raw materials	\$ 2,044,216	\$ 1,594,313
Work-in-process	1,581,687	1,506,565
Finished goods	809,189	169,800
Total	\$ 4,435,092	\$ 3,270,678

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.

## 7. 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 value of these indemnification agreements is minimal. The Company has no accrued warranties and has no history of claims paid.

## 8. Income Taxes

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 recorded a provision for taxes of \$938,367 and \$904,478 for the quarters ended June 30, 2006 and 2005, respectively. The Company recorded a provision for taxes of \$1,558,043 and \$1,720,486 related to the income for the six months ended June 30, 2006 and 2005, respectively. The effective tax rates were 41.1% and 40.4% for the three and six months ended June 30, 2006 and 2005, respectively. The adoption of SFAS 123R resulted in an increase in the 2006 effective tax rate as stock-based compensation expense related to incentive stock options are non-deductible until a disqualifying event occurs and the tax benefits are realized. The Company's taxes payable balance was \$574,513 at June 30, 2005. At December 31, 2005, \$276,721 of prepaid taxes was included in prepaid expenses.

## **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 efforts to increase sales of ophthalmic viscoelastic products and support of the distribution of ORTHOVISC® in the U.S. and internationally;
- our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;
- the timing of, scope of and rate of patient enrollment for clinical trials;
- our expectation with respect to reimbursements of ORTHOVISC products under J code;
- the level of our revenue or sales in particular geographic areas and/or for particular products;
- the market share for any of our products;
- our expectations of the size of the U.S. and European markets for osteoarthritis of the knee;
- our intention to increase market share for ORTHOVISC in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee;
- our ability and Galderma's ability to perform under the agreements entered into, and related development and commercialization of CTA products;
- our expectations that no additional clinical trials will be required related to CTA PMA and CE Mark supplements;
- our expectations for ophthalmic products revenue;
- our expectations regarding regular order flow for ORTHOVISC;
- 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;
- our expectations regarding HYVISC sales;

- our expectation to develop new distribution partners around the world;
- our expectations regarding costs related to the manufacturing facility;
- our expectation for increases in operating expenses;

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- our expectation for increases in capital expenditures;
- our expected tax rate and taxable revenues; and
- the rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy of such cash.

*Furthermore, additional statements identified by words such as will, likely, may, believe, expect, anticipate, intend, seek, designed, develop, would, future, can, could and other expressions that are predictions of or indicate 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 Risk Factors in the Company's Annual Report on Form 10-K. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed herein and in the Management's Discussions and Analysis of Financial Condition and Results of Operations beginning on page 14 of this Quarterly Report on Form 10-Q, as well as the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2005 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) develops, manufactures and commercializes therapeutic products for tissue protection and healing. 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; and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. 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 over 15 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. INCERT® is a HA based anti-adhesive for surgical applications.

Products in development include an HA based dermal filler used for cosmetic tissue augmentation (CTA) applications. In September 2005, we filed a Pre-Market Approval (PMA) application with the FDA seeking approval to market and sell our CTA product in the United States. We received CE marking approval for our CTA product in the first quarter of 2006. In June 2006, we entered into a license and development agreement with Galderma Pharma S.A. and a supply agreement with Galderma Pharma S.A. and Galderma S.A. for exclusive worldwide development and commercialization of CTA products. Galderma Pharma S.A. and Galderma S.A. are jointly referred to as Galderma. Galderma has requested that the Company make some product improvements that address cosmetic issues and the shelf life of the product. These improvements increase the competitiveness of the product both in Europe and the North American markets. These product and process modifications will require supplements to our PMA and CE Mark approvals. Since the modifications do not address safety or efficacy issues, we do not believe additional clinical trials will be required. Currently, Galderma is planning a worldwide launch of the enhanced version of the product in mid 2007.

#### *Osteoarthritis Business*

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

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 43.4% and 36.5%, respectively, of product revenue for the three and six months ended June 30, 2006 and increased 60.5% and 37% compared to the same three and six month periods of 2005. The increase was primarily due to increased sales to Turkey and Canada. We recently signed agreements with new distribution partners in Kuwait and Taiwan, but have not commenced sales in those countries pending the completion of product registration process. We expect international sales to grow in 2006 compared to 2005 reflecting further increased market penetration in

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certain of our existing markets as well as anticipated expansion into new international markets. For these new opportunities we have assessed the world market, and we continue to make progress in developing new distribution partnerships around the world.

ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is currently marketed by DePuy Mitek, Inc., a subsidiary of Johnson & Johnson, 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. Sales of ORTHOVISC in the U.S. contributed 17.6% and 15.7%, respectively, of our product revenue for the three and six months ended June 30, 2006 and increased 364.8% and 103.6% from the same three and six month periods of 2005. The significant increase is partially due to DePuy Mitek's underlying sales to end-users more than doubled in the second quarter of 2006 compared to the same period in 2005, and increased 57% from the first quarter of 2006. For the six month period of 2006, DePuy Mitek's sales to end-users were 80.2% higher than in the same period in 2005. Note that, due to initial overstocking of product by OBP in 2004, no units were sold to OBP/DePuy Mitek during the second quarter of 2005. DePuy Mitek's inventory levels have now been reduced to the point where we now expect our sales to DePuy Mitek to more closely follow their end-user sales pattern.

Sales of ORTHOVISC to end-users grew slower than anticipated since 2004 as a result of a number of factors. We believe that one of the key contributing factors to this slower growth has been reimbursement and the lack of receiving assignment of a specific reimbursement code. The Healthcare Common Procedure Coding System (HCPCS) is a comprehensive and standardized coding system that describes classifications of like products that are medical in nature by category for the purpose of efficient claims processing. HCPCS codes are assigned by the Centers for Medicare and Medicaid Services (CMS). As it is typical for a newly-introduced medical device, initial sales of ORTHOVISC were made without a unique reimbursement code and reimbursement submissions were made using a miscellaneous code with no specified reimbursement dollar value. We believe that using the miscellaneous reimbursement code without a specified reimbursement dollar value negatively impacted end-user sales of ORTHOVISC in 2004 and 2005. ORTHOVISC has a C-Code for hospital procedure reimbursement. The Company is operating under a miscellaneous J-Code for physician's office reimbursement for the balance of 2006. The CMS announced in April 2006 preliminary recommendations from its workgroup formed to study reimbursement for HA based osteoarthritis products. The workgroup has recommended that all HA Viscosupplement products be placed in one or two J-Code for 2007. A coding decision for 2007 is expected to be finalized during the second half of 2006. The continued required use of a miscellaneous J code may result in physician reluctance to utilize ORTHOVISC as compared to if a unique J code had been assigned. There can be no assurance regarding the future course CMS will set for ORTHOVISC reimbursement. DePuy Mitek is taking steps to assist in the reimbursement process in physicians' offices. Year-to-date, DePuy Mitek has tripled the size of its product specialist team from 13 professionals in the field across the country at the end of last year. These professionals were added to support DePuy Mitek's sales representatives and to provide hands-on assistance to the physicians' offices. We believe that these specialists are having a positive effect on domestic ORTHOVISC sales. DePuy Mitek also has developed a Web site for physicians office personnel as a resource for reimbursement issues.

Sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 3.1% and 6.8% of our product revenue for the three and six months ended June 30, 2006 and decreased 31% and increased 9.7% from the same three and six month periods of 2005. We continue to look at other veterinary applications and opportunities to expand geographic territories. We expect HYVISC sales for 2006 to decrease slightly from 2005 levels.

#### *Ophthalmic Business*

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. Sales of ophthalmic products contributed 35.8% and 41% of our product revenue for the three and six months ended June 30, 2006 and increased 62.1% and 26.4% from the same three and six month periods of 2005. Sales to Bausch & Lomb accounted for 90.6% and 91.5% of ophthalmic sales for the three and six months ended June 30, 2006 and contributed 32.4% and 37.5% of product revenue for the three and six month periods of 2006. We expect ophthalmic product sales for 2006 to increase moderately from 2005 levels.

#### *Research and Development*

Our CTA product is based on a family of chemically modified, cross-linked forms of HA designed for longer duration in the body. Cosmetic tissue augmentation is a therapy designed as a soft tissue filler for facial wrinkles, scar remediation and lip augmentation. Our HA based dermal filler is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. In October 2005, we substantially completed a pivotal U.S. clinical trial to evaluate CTA's effectiveness for correcting nasolabial folds. The trial was conducted by dermatologists and plastic surgeons at 10 centers throughout the U.S. The six month primary endpoint results of this trial were submitted to the U.S. Food and Drug Administration (FDA) in a Pre-Market Approval (PMA) application in September 2005. In the first quarter of 2006, we received CE mark approval to market



our CTA product in the European Union. During the first quarter of 2006, we commenced a European follow-on CTA trial. Enrollment in the trial has been completed and a 6 month follow up is expected to be completed in the fourth quarter of 2006.

On June 30, 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Galderma, for the exclusive worldwide development and commercialization of hyaluronic acid based CTA products. Under the agreements, the Company will be responsible for the development and manufacturing of the CTA products, and Galderma will be responsible for the commercialization, including distribution and marketing, of the CTA products worldwide. Galderma has requested that the Company make some product improvements that address cosmetic issues and the shelf life of the product. These improvements are expected to increase the competitiveness of the product both in the European and the North American markets. These product and process modifications will require supplements to our PMA and CE Mark approvals. Since the modifications do not address safety or efficacy issues, we do not believe additional clinical trials will be required. Currently, Galderma is planning a worldwide launch of the enhanced version of the product in mid 2007.

INCERT-S is our product designed to reduce post-surgical fibrosis following spinal surgery. We completed a pilot human clinical trial in Europe in December 2005 involving patients undergoing spinal surgery, and the results of the clinical trial demonstrated safety.

#### ***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 June 30, 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.

On June 30, 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Galderma for the exclusive worldwide development and commercialization of hyaluronic acid based CTA products. Under the agreements, the Company will be responsible for the development and manufacturing of the CTA products, and Galderma will be responsible for the commercialization, including distribution and marketing, of the CTA products worldwide. The agreements include an up front payment, milestones upon achievement of predefined regulatory goals, funding of ongoing development activities, payments for supply of CTA products, royalties on sales and sales threshold achievement payments for meeting certain net sales targets. The Company will account 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 recorded as deferred revenue as of June 30, 2006.

Milestone payments under the agreements are related to final regulatory approvals of the CTA products in the United States and Europe. Achievements of regulatory approvals would entitle the Company to aggregate milestone payments of up to \$5,000,000 for the initial CTA product and up to an additional \$1,500,000 for each additional CTA product that the parties agree to develop and market. In addition, the agreements contain payment terms for supplying Galderma with CTA products and royalties based on sales of the Company's CTA products by Galderma to its customers. The agreements provide for sales threshold achievement payments of up to \$14,500,000 if CTA product net sales exceed certain net sales targets. Under the terms





of the agreements, Galderma will support the development of the Company's CTA products, including reimbursement for certain development costs for the enhancement of the initial CTA product, 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 CTA 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.

*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). 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. The Company elected to adopt the modified prospective transition method as provided by SFAS 123R and, accordingly, financial statement amounts for the prior periods presented in this Form 10-Q have not been restated to reflect the fair value method of expensing share-based compensation.

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 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.

Prior to 2006, the Company granted stock options to employees and members of the Board of Directors. In the first quarter of 2006, the Company granted 94,850 shares of share-based stock appreciation rights to members of its Board of Directors and company officers. The Company also granted 12,500 shares of stock options and 10,500 shares of restricted stock to non-officer employees during the first quarter of 2006. During the second quarter 2006, the Company granted 5,000 shares of share-based stock appreciation rights to an employee. These awards were granted under the Stock Option and Incentive Plan approved by the Board of Directors on April 4, 2003. See Note 4 to consolidated financial statements for details.

*Deferred tax assets.*

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 June 30, 2006, 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**

*Product revenue.* Product revenue for the quarter ended June 30, 2006 was \$7,115,484, an increase of \$3,031,352, or 74.2%, compared to \$4,084,132 for the quarter ended June 30, 2005. Product revenue for the six months ended June 30, 2006 was \$13,381,318, an increase of \$3,620,249, or 37.1%, compared to \$9,761,069 for the six months ended June 30, 2005.

**Three Months Ended June 30,  
(in thousands)**

	2006	2005	Increase (Decrease)	
			\$	%
Ophthalmic Products	\$ 2,545,170	\$ 1,569,822	\$ 975,348	62.1 %
ORTHOVISC	4,337,094	2,191,750	2,145,344	97.9 %
HYVISC	222,720	322,560	(99,840 )	-31.0 %
INCERT	10,500		10,500	
	\$ 7,115,484	\$ 4,084,132	\$ 3,031,352	74.2 %

**Six Months Ended June 30,  
(in thousands)**

	2006	2005	Increase (Decrease)	
			\$	%
Ophthalmic Products	\$ 5,482,340	\$ 4,338,477	\$ 1,143,863	26.4 %
ORTHOVISC	6,978,518	4,593,130	2,385,388	51.9 %
HYVISC	909,960	829,462	80,498	9.7 %
INCERT	10,500		10,500	
	\$ 13,381,318	\$ 9,761,069	\$ 3,620,249	37.1 %

The increase in Ophthalmic product sales for the three and six months ended June 30, 2006 is primarily attributable to increased sales to Bausch & Lomb. Sales to Bausch & Lomb increased 89.6% and 34.7% for the three and six month periods ended June 30, 2006 compared to the same periods last year. Ophthalmic product sales for the three and six months ended June 30, 2005 were negatively impacted by a voluntary product recall that reduced Ophthalmic sales in the second quarter of 2005 by \$1,359,000. Sales to Bausch & Lomb contributed 32.4% and 37.5% of product revenue for the three and six month periods ended June 30, 2006. The increase in sales during the first half of 2006 is primarily related to Bausch & Lomb's ordering patterns and is not indicative of results for the remainder of 2006.

The increase in ORTHOVISC sales for the three and six months ended June 30, 2006, is primarily due to an increase in international sales to our distributors in Turkey and Canada, and an increase in unit sales in the U.S. to our distribution partner DePuy Mitek. International sales of ORTHOVISC were 43.4% and 36.5% of product sales for the three and six month periods ended June 30, 2006, an increase of 60.5% and 37% from the same period last year. Sales of ORTHOVISC to our U.S. distributor, DePuy Mitek, were 17.6% and 15.7% of product sales for the three and six month periods ended June 30, 2006, an increase of 364.8% and 103.6% from the same period last year. Along with the lack of unit sales to DePuy Mitek in the second quarter of 2005, DePuy Mitek's underlying sales to end-users more than doubled in the second quarter of 2006 compared to the same period in 2005, which together were the primary reason for the increase. For the six month period of 2006, DePuy Mitek's sales to end-users were 80.2% higher than the same period in 2005. DePuy Mitek's inventory levels have now been reduced to the point where we now expect our sales to DePuy Mitek to more closely follow their end-user sales pattern.

HYVISC sales decreased 31% for the quarter ended June 30, 2006 compared to the same period last year. For the six months ended June 30, 2006, HYVISC sales increased 9.7% compared to the same period last year. HYVISC sales contributed 3.1% and 6.8% of product revenue for the three and six months ended June 30, 2006. The decrease in sales during the second quarter of 2006 was due to timing differences in customer order pattern. Despite the increase in sales for the six months ended June 30, 2006, we expect sales of HYVISC to decrease slightly in 2006 from 2005 based on current customer orders.

INCERT is a HA based anti-adhesive for surgical applications. CE marking approval for commercial marketing and sale was received in the third quarter of 2004. During the second quarter of 2006, the Company sold \$10,500 of its INCERT product in the United Kingdom through our distributor Surgicraft Limited. The Company also recently signed a distribution agreement with a current ORTHOVISC partner in Greece for

the INCERT product.

*Licensing, milestone and contract revenue.* Licensing, milestone and contract revenue for the three and six months ended June 30, 2006 was \$682,557 and \$1,369,684, compared to \$2,935,293 and \$4,549,643 for the same period last year. For the first six months

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of 2006, licensing and milestone revenue includes the ratable recognition of the \$27,000,000 in up-front and milestone payments from Ortho Biotech. These amounts are being recognized in income ratably over the ten-year expected life of the agreement, or \$675,000 per quarter. Licensing, milestone and contract revenue in the second quarter and first six months of 2005 included \$2,248,165 and \$3,166,519, respectively, of contract revenue in connection with our development and commercialization contract with OrthoNeutrogena for its hyaluronic acid-based cosmetic tissue augmentation product. This contract was terminated in the third quarter of 2005.

*Product gross profit.* Product gross profit for the quarter ended June 30, 2006 was \$4,224,580, or 59.4% of product revenue, an increase of \$2,257,656, or 115%, from gross profit of \$1,966,924 representing 48.2% of product revenue, for the quarter ended June 30, 2005. Product gross profit for the six months ended June 30, 2006 was \$7,442,596, or 55.6% of product revenue, an increase of \$2,792,699, or 60%, from gross profit of \$4,649,897, representing 47.6% of product revenue, for the six months ended June 30, 2005. The increase in product gross profit is due primarily to higher production volume, lower raw material prices, and favorable product mix shift. Furthermore, the three and six month periods in 2005 were adversely impacted by costs incurred from the prior year's voluntary Ophthalmic product recall.

*Research & development.* Research and development expenses for the quarter ended June 30, 2006 was \$1,129,877 a decrease of \$330,293, or 22.6%, compared to \$1,460,170 for the quarter ended June 30, 2005. Research and development expenses for the six months ended June 30, 2006 was \$2,206,669 a decrease of \$452,710 or 17%, compared to \$2,659,379 for the six months ended June 30, 2005. Research and development expenses include costs associated with our in-house research and development efforts for the development of CTA product enhancements and next generation product for our HA-based technology, the costs of clinical trials, and the preparation and processing of applications for regulatory approvals at various relevant stages of development. The decrease in research and development expenses for the three and six months ended June 30, 2006 is primarily attributable to the completion of the pivotal CTA clinical trial during the fourth quarter of 2005, partially offset by costs related to a smaller scale European follow-on CTA trial commenced during the first quarter of 2006, as well as recording of stock-based compensation expense of \$67,700 and \$121,293 for the three and six month periods ended June 30, 2006, as a result of adoption of SFAS 123R effective January 1, 2006. We expect increases in research and development costs going forward related to the Company's next generation ORTHOVISC products.

*Selling, general & administrative.* Selling, general and administrative expenses for the three months ended June 30, 2006 was \$1,976,600, an increase of \$501,436, or 34%, compared to \$1,475,164 for the same periods last year. Selling, general and administrative expenses for the six months ended June 30, 2006 was \$3,765,599, an increase of \$998,360, or 36.1%, compared to \$2,767,239 for the same periods last year. The increase in selling, general and administrative expenses is due primarily to recording of stock-based compensation expense of \$210,543 and \$469,593 for the three and six months ended June 30, 2006 as a result of adoption of SFAS 123R effective January 1, 2006. Selling, general and administrative expenses for the quarter also reflected increases in legal costs due to the Galderma agreements for approximately \$121,000 and personnel costs of approximately \$72,000. Increase in selling, general and administrative expenses for the six month period in 2006 from 2005 reflected increases in legal costs incurred in connection with the Galderma agreements for approximately \$189,000, and personnel costs of \$161,000.

*Interest income.* Interest income for the three months ended June 30, 2006 was \$489,772, an increase of \$215,688, or 78.7%, compared to \$274,084 for the same periods last year. Interest income for the six months ended June 30, 2006 was \$950,846, an increase of \$464,553 or 95.5%, compared to \$486,293 for the same periods last year. The increase is primarily attributable to higher interest rates as a result of the numerous Federal Reserve increases, and higher cash balances.

*Income taxes.* Provision for income taxes was \$938,367 and \$904,478 related to income for the quarters ended June 30, 2006 and 2005, respectively. The Company recorded a provision for income taxes of \$1,558,043 and \$1,720,486 for the six months ended June 30, 2006 and 2005, respectively. The effective tax rate for the provision in the three and six months ended June 30, 2006 were 41.0% and 41.1%, respectively. The effective tax rate for the provision for the three and six months ended June 30, 2005 was approximately 40.4%. The adoption of SFAS 123R resulted in an increase in the 2006 effective tax rate as stock-based compensation expense related to incentive stock options are non-deductible until a disqualifying event occurs and the tax benefits are realized.

**LIQUIDITY AND CAPITAL RESOURCES**

We require cash to fund our operating expenses and capital expenditures. We expect that our requirement for cash to fund these uses will increase as the scope of our operations expands. Historically we have funded our cash requirements from available cash and investments on hand. At June 30, 2006, cash and cash equivalents totaled \$46,127,054 compared to \$44,746,656 at December 31, 2005.

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Cash provided by operating activities was \$1,621,890 for the six months ended June 30, 2006 compared with \$415,196 for the six months ended June 30, 2005. Cash provided by operating activities for the first half of 2006 increased by \$1,206,694 from the same period in 2005. Increase in cash from operating activities for the first half of 2006 was primarily due to net income of \$2,232,815, non-cash expenditures of \$936,382, and the receipt of an upfront payment of \$1,000,000 from Galderma, offset by a net cash usage from other operating assets and liabilities of \$2,547,307. Major causes for net cash usage from operating assets and liabilities during the first six months of 2006 include an increase in inventory due to the Company's decision to increase inventory to more timely respond to customer opportunities; increase in accounts receivable as a result of increase in sales in 2006; and decreases in accounts payable and accrued expenses reflecting vendor and employee related payments during the first quarter of 2006. The decrease in deferred revenue reflects the amortization of upfront and milestone payments from Ortho Biotech. Overall working capital increased to \$48,998,577 at June 30, 2006 from \$46,583,396 at December 31, 2005.

Cash used in investing activities was \$1,032,056 for the six months ended June 30, 2006. Cash used in investing activities was \$326,063 for the six months ended June 30, 2005. Cash used in investing activities for 2006 primarily reflects capital expenditures for manufacturing equipment and construction costs to build a new manufacturing suite within our existing manufacturing facility in connection with our new CTA product, and computer equipment to expand operational functionality. We expect to increase our capital expenditures in 2006 over 2005 levels primarily to complete the upgrade and expansion of our manufacturing and packaging equipment. Since January 2005, the company has incurred approximately \$2,200,000 related to the upgrade and expansion of the manufacturing facility for the CTA product. The Company has substantially completed its facility build-out and manufacturing equipment acquisition as of June 30, 2006.

Cash provided by financing activities of \$790,564 and \$502,042 for the six months ended June 30, 2006 and 2005, respectively, reflected the proceeds from exercises of stock options and tax benefits from such exercises.

#### ***Recent Accounting Pronouncements***

In July 2006, the FASB issued FIN 48 Accounting for Uncertainty in Income Taxes. This interpretation requires that we recognize in our financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

In May 2005, the FASB, as part of an effort to conform to international accounting standards, issued SFAS No. 154, Accounting Changes and Error Corrections, (SFAS 154). SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 or beginning on July 1, 2006. SFAS 154 requires that all voluntary changes in accounting principles be retrospectively applied to prior financial statements as if that principle had always been used, unless it is impracticable to do so. When it is impracticable to calculate the effects on all prior periods, SFAS 154 requires that the new principle be applied to the earliest period practicable. SFAS 154 also redefines restatement as the revising of previously issued financial statements to reflect the correction of an error. The adoption of SFAS 154 did not have a material effect on our financial position or results of operations.

### **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, 2005.

As of June 30, 2006, 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. All of our investments consist of money market funds, commercial paper and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

#### ***Primary Market Risk Exposures***

Our primary market risk exposures are in the areas of interest rate risk. Our investment portfolio of cash equivalent 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.

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (Exchange Act), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that material information relating to us required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures. We currently are in the process of further reviewing and documenting our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls.

There were no changes in our internal control over financial reporting during the second quarter of fiscal year 2006 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, 2005, 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.

The two risk factors below were disclosed on the Form 10-K for year ended December 31, 2005 and have been updated to provide additional information related to the agreements we entered into with Galderma on June 30, 2006 and our sales dependency on third party reimbursements:

***FDA or other governmental approvals for our products may materially adversely affect our business, results of operations and financial condition.***

Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA will grant approval for our new products on a timely basis if at all, or that FDA review will not involve delays that will adversely affect our ability to commercialize additional products or expand permitted uses of existing products, or that the regulatory framework will not change, or that additional regulation will not arise at any stage of our product development process which may adversely affect approval of or delay an application or require additional expenditures by us. In the event our future products are regulated as human drugs or biologics, the FDA's review process of such products typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

Our HA products under development, including a product for the cosmetic tissue augmentation market (CTA) have not obtained U.S. regulatory approval for commercial marketing and sale. We received CE marking approval for our initial CTA product in the first quarter of 2006. In addition, we filed a pre-market approval application for our initial CTA product in September 2005 for our CTA product. On June 30, 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Galderma, for the exclusive worldwide development and commercialization of hyaluronic acid based CTA products. Galderma has requested that the Company make some product improvements that address cosmetic issues and the shelf life of the product. These improvements are expected to increase the competitiveness of the product both in the European and the North American markets. These product and process modifications will require supplements to our PMA and CE Mark approvals.

We cannot assure you that in the Company's product development efforts:

- we will begin or successfully complete clinical trials for new products;
- the clinical data will support the efficacy of these products;
- we will be able to successfully complete the FDA or foreign regulatory approval process, where required; or
- additional clinical trials will support a PMA application and/or FDA approval or other foreign regulatory approvals, where required, in a timely manner or at all.

We also cannot assure you that any delay in receiving FDA approvals will not adversely affect our competitive position. Furthermore, even if we do receive FDA approval:

- the approval may include significant limitations on the indications and other claims sought for use for which the products may be marketed;
- the approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements; and
- meaningful sales may never be achieved.

*Sales of our products are largely dependent upon third party reimbursement and our performance may be harmed by health care cost containment initiatives and changes in reimbursement related laws and regulations.*

In the U.S. and other markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third party payers, including Medicare, Medicaid, other health insurance and managed care plans, and government agencies to reimburse all or part of the cost of the health care product. We depend upon the distributors for our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payers may depend on a number of factors, including the payer's determination that the use of our products is clinically useful and cost-effective, medically necessary and not experimental or investigational. There can be no assurance that third party reimbursement coverage will be available or adequate for any products or services developed by us. Outside the U.S., the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems. Reimbursement laws and regulations may change from time to time. Lack of adequate coverage and reimbursement provided by governments and other third party payers for our products and services could have a material adverse effect on our business, financial condition, and results of operations.

**Item 4. Submission of Matters to a Vote of Security Holders**

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On June 1, 2006, we held our 2006 Annual Meeting of Stockholders. At our annual meeting, stockholders were asked to consider one proposal: to elect two (2) Class I Directors, each to serve until the 2009 Annual Meeting of Stockholders and until their respective successors are duly elected and qualified. With respect to this proposal, Joseph L. Bower and Eugene A. Davidson, Ph.D., were nominated as Class I Directors of Anika. Dr. Bower received 8,875,414 shares voted in favor of his election and 1,014,354 votes were withheld. Dr. Davidson received 9,053,413 shares voted in favor of his election and 836,355 votes were withheld. Drs. Bower and Davidson were therefore elected as Class I Directors. Dr. Harvey S. Sadow and Raymond J. Land (Class II Directors), and Steven E. Wheeler and Charles H. Sherwood, Ph.D. (Class III Directors) continued to serve their respective terms after the Annual Meeting of Stockholders.

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**Item 6. Exhibits**

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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.
(10) Material Contracts	
+*10.1	License and Development Agreement between Anika Therapeutics, Inc. and Galderma Pharma S.A., dated as of June 30, 2006.
+*10.2	Supply Agreement among Galderma S.A, Galderma Pharma S.A, and Anika Therapeutics, Inc., dated as of June 30, 2006.
(11) Statement Regarding the Computation of Per Share Earnings	
*11.1	See Note 5 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.

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\* Filed herewith.

\*\* Furnished herewith.

+ Certain portions of this document have been omitted pursuant to a confidential treatment request filed with the Securities and Exchange Commission. The Omitted portions have been filed separately with the Securities and Exchange Commission.

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**SIGNATURES**

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

ANIKA THERAPEUTICS, INC.

August 7, 2006

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

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